Risk Factors Comparison 2025-03-20 to 2024-03-20 Form: 10-K

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

Risks Related to Our Financial Position and Capital Needs We are a clinical- stage biopharmaceutical company with a limited operating history. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability. We are a clinical- stage biopharmaceutical company with a limited operating history, and we are in the early stages of our **product** development efforts. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain marketing authorization and become commercially viable. ~~We~~ **Currently, we** have no products approved for commercial sale and ~~have~~ **are** not ~~generated~~ **generating** any revenue from product sales. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of our product candidates, securing related intellectual property rights and conducting discovery, research and development activities for our programs. We have incurred net losses each year since inception through to December 31, 2021. For the year ended December 31, 2022, we generated net income of $ 5. 3 million, primarily as a result of revenues **(royalties / milestone payments)** arising from AstraZeneca sales of Vaxzevria and our agreement with OUI. For the ~~year~~ **years** ~~ended~~ **ending** December 31, **2024 and** 2023, we incurred net losses of $ **61. 2 million and $** 73. 4 million **, respectively** . As of December 31, **2024 and** 2023 ~~and 2022~~ , we had an accumulated deficit of $ **237. 7 million and $** 176. 6 ~~million and $ 103. 2~~ million, respectively, and we do not currently expect profits or positive cash flows from operations in the foreseeable future. We anticipate that our expenses will increase substantially if, and as we: **• pursue the clinical and preclinical development of our current product candidates; • use our technologies to advance additional product candidates into preclinical and clinical development;** • seek marketing authorizations for product candidates that successfully complete clinical trials, if any; • **attract, hire and retain additional clinical, regulatory, quality control and other personnel; •** conduct preclinical studies and clinical trials for our current and future product candidates based on our proprietary biologic and synthetic platforms, including the Chimpanzee Adenovirus Oxford (" ChAdOx") and Modified vaccinia Ankara (" MVA"), vectors, SNAP- TI, SNAP- CI and our other technologies; • expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; • establish our manufacturing capabilities through third parties or by ourselves and scale- up manufacturing to provide adequate supply for clinical trials and commercialization; • expand, maintain, protect and enforce our intellectual property portfolio; • establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or ~~jointly~~ **through a selected partner** ; • acquire or in- license other product candidates and technologies **for development and commercialization** ; and • incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development costs and other expenditures to develop and market additional product candidates and we may never generate revenue that is significant or large enough to achieve profitability. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital **unless and until such losses are eliminated by revenue** . If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Accordingly, our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment. We have not yet generated any material revenue from our **current** product candidates. Our ability to become profitable depends upon our ability to generate revenue. We do not expect to generate significant revenue from our current or future product candidates unless or until we successfully complete clinical development and obtain marketing authorization for, and then successfully commercialize, at least one of our product candidates. Certain of our product candidates are in the preclinical stages of development and will require additional preclinical studies, and all of our product candidates will require additional clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We have not yet administered certain of our product candidates to humans and, as such, we face significant translational risk as our product candidates advance into and through the clinical stage, as promising results in preclinical studies may not be replicated in subsequent clinical trials, and testing on animals may not accurately predict human experience. Our ability to generate revenue depends on a number of factors, including, but not limited to: • timely completion of our manufacturing, preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third- party contractors; • delays out of our control, such as participant willingness to enroll **in our clinical trials** ; • our ability to complete ~~IND~~ **INDs** , enabling trials and successfully submit INDs or comparable applications, for our product candidates; • whether we are required by the FDA, the EMA, or the MHRA or similar foreign regulatory authorities, to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates; • our ability to demonstrate to the satisfaction of the FDA and similar

foreign regulatory authorities the safety, potency, purity, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates and such regulatory authorities' acceptance of our development strategy; • the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any; • the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities; • the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional approaches, including antivirals, immune modulators **, monoclonal antibodies** , siRNA, CRISPR editing, capsid inhibitors, novel entry inhibitors, or other small molecules, RNA, DNA, nanoparticle, VLP, peptide, protein, whole- killed or other vaccine technologies; • the actual and perceived availability, cost, risk profile and side effects and efficacy of our product candidates, if approved, relative to existing and future alternative immunotherapies, therapeutic and prophylactic vaccines and competitive product candidates and technologies; our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP; • our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; • patient demand for our product candidates and any future product candidates, if approved; • our ability to establish, maintain, protect and enforce intellectual property rights in and to our product candidates or any future product candidates; • the ability of our licensees and collaborators to develop and commercialize our products effectively; • the risk that some or all of the patients that receive **the AstraZeneca product** Vaxzevria develop neutralizing antibodies against ChAdOx, which could limit the immunological response from subsequent dosing with one of our **viral vector** product candidates; • the possibility that immunogenicity **of our viral vectors or immune tolerance with SNAP- TI** may not translate into clinical benefit; and • the increased costs and complexities associated with manufacturing **;** and • funding for the development of product candidates contributed by third parties, such as CRUK, CEPI and CanSino, whether spent directly by them or by grant or other funding into our company. Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining marketing authorizations for, or commercializing, our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding. If we engage in acquisitions or future strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may evaluate acquisitions and strategic partnerships in the future, including licensing or acquiring complementary product candidates, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including: • increased operating expenses and cash requirements; • the assumption of indebtedness or contingent liabilities; • the issuance of our equity securities which would result in dilution to our **existing** shareholders; • assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel; • the diversion of our management' s attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership; • retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates to achieve marketing authorizations; and • ~~our inability~~ **a failure** to generate revenue from acquired intellectual property, technology and / or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs. In addition, we may assume or incur debt obligations, incur large one- time expenses and / or acquire intangible assets that could result in significant future amortization expense. Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We are a clinical- stage biopharmaceutical company with no approved products and a limited operating history. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, filing patent applications, identifying potential product candidates, undertaking preclinical studies, in- licensing product candidates for development, and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials, as well as sponsoring and conducting clinical trials up to Phase 2b. We have not yet demonstrated our ability to successfully complete clinical trials beyond Phase 2b, obtain marketing approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, ~~as a young business,~~ we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting additional commercial activities. We may not be successful in such a transition. We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations. We are currently advancing current and future product candidates based on our proprietary biologic and synthetic platforms, including the ChAdOx and MVA vectors, SNAP- TI, ~~SNAP- CI~~ and our other technologies through clinical development. Developing and commercializing products for therapeutic indications is expensive, and we do not expect to generate meaningful product revenues in the foreseeable future. As of December 31, ~~2023~~ **2024** , our cash ~~and~~ **,** cash equivalents **and restricted cash** were $ ~~142~~ **112** . ~~1~~ **4** million. Based on our current business plan, our management believes that we have sufficient cash **and other financial resources** to support our operations into the **start** ~~fourth quarter~~ of ~~2025~~ **2027** , without additional financing. Our fundraising efforts to raise additional capital may divert our management from their day- to-

day activities, which may adversely affect our ability to develop our platforms. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our **existing** shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute our **existing** stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to obtain funding on a timely basis, we may be required to revise our **current** business plan and strategy, which may result in us significantly curtailing, delaying or discontinuing one or more of our clinical trials, decreasing headcount or may result in our being unable to expand our operations or otherwise capitalize on our business opportunities. As a result, our business, financial condition and results of operations could be materially affected. Raising additional capital may cause dilution to our **existing** shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of ordinary shares, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti- dilution protections that could adversely affect your rights as a common shareholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day- to- day activities, which may adversely affect our management' s ability to oversee the development of our product candidates. If we raise additional funds through collaborations, strategic alliances, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to **third parties to** develop and market **our** product candidates that we would otherwise prefer to develop and market ourselves. We may require substantial additional funding in the future. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts. Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our ~~platform~~ **platforms** and our product candidates developed using our ~~platform~~ **platforms** . Preclinical studies, clinical trials and additional research and development activities will require substantial funds to complete. We expect ~~our~~ **the research and development** expenses **for our programs** to increase in parallel with ~~our~~ **the** ongoing activities, particularly as we continue our preclinical and clinical development activities to identify new product candidates and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to **product launch,** product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. However, we have estimated our current additional funding needs based on assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. If we are unable to raise capital or generate revenue when needed or on attractive terms, we would be forced to delay, reduce or eliminate our discovery and preclinical development programs or any future commercialization efforts. We had cash ~~and~~ **,** cash equivalents **and restricted cash** of $ ~~142~~ **112** . ~~1~~ **4** million as of December 31, ~~2023~~ **2024** . Our future capital requirements will depend on many factors, including: • the scope, progress, results and costs of **researching and developing our current and future product candidates and programs, and of conducting** preclinical ~~development~~ **studies** and clinical trials ~~for our~~ **; • the number and development requirements of other** product candidates **that we may pursue, and of other indications for our current product candidates that we may pursue** ; • the ~~extent to which~~ **stability, scale and yield of future manufacturing processes as** we ~~enter into additional collaboration arrangements with regard to~~ **scale- up production and formulation of our** product ~~candidate~~ **candidates either internally or externally for later stages of** development **and commercialization** ~~or acquire or in- license products or technologies~~ ; • the **timing of, success achieved and the** costs **involved in obtaining** ~~, timing and outcome of~~ regulatory ~~review of~~ **and marketing approvals and developing our ability to establish license** ~~our~~ **or sale transactions and / or sales and marketing capabilities, if any, for our current and future** product candidates **if clinical trials and approval**

processes are successful; • the success of our collaborations with CEPI, Oxford University / OUI, Arbutus, CanSino, CRUK and the Ludwig Institute and any future collaboration partners; • our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements ; • the costs of future commercialization activities, including product **launch, product** sales, marketing, manufacturing and distribution, for any of our **current and future** product candidates for which we receive marketing approval; • ~~revenue~~ **the timing** , **receipt and amount of** ~~if any, received from~~ commercial sales ~~of~~ **revenues, milestones** ~~our~~ **or royalties or other income from, our future** ~~product~~ **products** ~~candidates~~ , should any of our product candidates receive marketing approval; ~~and~~ • the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, enforcing and protecting our intellectual property rights and defending intellectual property- related claims including litigation costs and any damages awarded in such litigation **; and • the emergence and success or otherwise of competing autoimmune or infectious disease therapies and other market developments** . Identifying potential product candidates, manufacturing them and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. Recent volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our ordinary shares or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets. Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new product candidates, **maintain optimal** ~~retain or expand our current~~ levels of personnel, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to: ● finance unanticipated working capital requirements; ● develop or enhance our technological infrastructure and our existing solutions; ● pursue acquisitions or other strategic relationships; and ● respond to competitive pressures. Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our ordinary shares. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital- raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations. Actual **national and international** events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. ~~For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (" FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank was swept into receivership.~~ Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have financial arrangements directly, or the financial services industry or **the global** economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services **industry or the life sciences** industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry **or life sciences industry** generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: • Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; • Delays, inability or reductions in our ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; • Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; or • Termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial

and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services **industry or life sciences** industry could lead to losses or defaults by our third- party manufacturers or suppliers, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. For example, a third- party manufacturer or supplier may default under their agreements with us, become insolvent or declare bankruptcy, or determine that they will no longer deal with us as a customer. In addition, a third- party manufacturer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any third- party manufacturer or supplier bankruptcy or insolvency, or any breach or default by a third- party manufacturer or supplier, or the loss of any significant third- party manufacturer or supplier relationships, could result in material losses to us and may have a material adverse impact on our business. ~~Actual payments we may receive in connection with certain milestones or net sales under the AstraZeneca License Agreement may differ from those described in this Annual Report, and there can be no assurance that we will receive any such payments at all. We received a share of certain milestones and royalties on net sales of certain vaccines under the research collaboration and exclusive worldwide license agreement (the" AstraZeneca License Agreement"), between Oxford University Innovation Limited (" OUI") and AstraZeneca UK Limited (" AstraZeneca"), through to the second quarter of 2023, however there can be no assurance as to the timing or amount of any such milestones or royalties on future net sales. In particular, we are not party to the AstraZeneca License Agreement, and we do not have any direct claim against AstraZeneca to receive a share of any milestones or net sales, or any other payments under the AstraZeneca License Agreement. Instead, we are party to the amendment, assignment and revenue share agreement, or the OUI License Agreement Amendment, with OUI, to the license agreement we entered into with OUI in March 2016, pursuant to which OUI agreed to pay us approximately 24 % of payments, including royalties and milestones, received by OUI in connection with the commercialization of any ChAdOx1 vector- based or ChAdOx2 vector- based vaccine in the field of SARS- CoV2 covered by or disclosed in the assigned patent application. As a result, we will only receive a share of any milestones or royalties paid on net sales of any such vaccine under the AstraZeneca License Agreement if, and to the extent that, OUI receives a share of any such milestones or royalties pursuant to that agreement. Our understanding of the terms of the AstraZeneca License Agreement is based solely on an extract of the agreement provided by the parties to that agreement. We are not a party to the AstraZeneca License Agreement and do not have access to a copy of that agreement to verify such extract. In addition, no party to the AstraZeneca License Agreement has confirmed that there are no material terms in that agreement that could adversely impact the economic and other terms of the AstraZeneca License Agreement. Moreover, there can be no assurance that the AstraZeneca License Agreement is an enforceable agreement, that the parties thereto will comply with their obligations under the agreement (including any obligations of AstraZeneca to make milestone or royalty payments to OUI), that the agreement will not be terminated pursuant to its terms or otherwise, or that the terms of the agreement (including royalty rates and other economic terms) will not be modified by the parties in the future. Accordingly, these and other factors could cause amounts received by OUI pursuant to the AstraZeneca License Agreement, and accordingly any share of the revenue under that agreement that we may receive, to fluctuate. Any such fluctuations could be material. Additionally, our understanding of the terms of the AstraZeneca License Agreement is that AstraZeneca is required to notify OUI of OUI' s shares of milestone and royalty payments within 30 days following the close of a fiscal quarter. OUI is then required to notify us of our share of the payments within 30 days after the end of a quarter when OUI received such milestone or royalty payments from AstraZeneca. If the required notifications are not made in accordance with the terms of the agreements, we may not be able to recognize revenue in the period in which it is earned. In addition, the announcement of adverse events observed in individuals who receive Vaxzevria and any negative impact on the perceptions of Vaxzevria safety may reduce sales of the vaccine and AstraZeneca may decide not to market Vaxzevria, and therefore reduce the potential payments that we would receive from royalties paid on net sales of Vaxzevria. Any association of Vaxzevria with adverse events, or the perception of such association, may otherwise adversely impact the development of, and our ability to commercialize, any of our product candidates.~~ Risks Related to Our Business and Industry and Risks Related to Clinical Development If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval or reimbursement and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed. All of our product candidates are in early stages of development, including our lead product ~~candidates~~ **candidate** VTP- **1000** ~~300 and VTP- 200~~, and as such will require extensive preclinical and clinical testing, as applicable. Product candidates may not meet targeted clinical or safety endpoints during clinical trials such as the MVA- based influenza vaccine candidate, VTP- 100, which did not meet defined primary clinical endpoints in two concurrent Phase 2b trials and we subsequently discontinued further development of this program. Our ~~product candidate VTP- 1100 in HPV cancer was paused in January 2024 to prioritize the other pipeline candidates already in the clinic, and the advancement of VTP- 1100 may depend on our ability to fund or how we prioritize our pipeline. Our~~ ability to generate product revenues, which we do not expect to occur for several years, if ever, will depend heavily on the successful development and eventual commercialization or out- license of the product candidates we develop, which may never occur. Before we are able to generate any revenues from product sales, our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of preclinical, clinical, and manufacturing activities, marketing approval in the United States and other markets, **the** ~~demonstrating~~ **demonstration of** effectiveness to pricing and reimbursement authorities, **the** obtaining **of** sufficient manufacturing supply **of product** for both clinical development and commercial ~~production~~ **sales** , **the** building of a commercial organization, and substantial investment

~~and~~ **in** significant marketing efforts **for product launch** . The success of our current and future product candidates will depend on several factors, including the following: • successful completion, with sufficient safety and efficacy profiles, of preclinical studies and clinical trials; • sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; • acceptance of INDs or equivalent clinical trial authorizations in other regions for our planned clinical trials or future clinical trials; • successful enrollment and completion of our ongoing and future clinical trials; • sufficient data from our clinical program that support an acceptable risk- benefit profile of our product candidates in the intended populations; • receipt and maintenance of marketing authorizations from applicable regulatory authorities; • scale- up of our manufacturing processes and formulation of our product candidates for later stages of development and commercialization; • establishing our own manufacturing capabilities or agreements with third- party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved; • ability to develop product candidate designs and formulations that provide sufficient genetic and thermal stability for long term storage and shipment to meet market requirements; • entry into collaborations, where needed, to further the development of our product candidates; • obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; • ~~successfully~~ -- **successful** ~~launching~~ --- **launch** ~~commercial sales~~ of our product candidates, if and when approved **to generate product sales** ; • acceptance of the product candidate' s benefits and uses, if and when approved, by patients, the medical community and third-party payors; • the prevalence and severity of adverse events experienced with our product candidates; • maintaining a continued acceptable benefit / risk profile of the product candidates following authorization; • effectively competing with other therapies, including new therapies that may be developed and approved; • obtaining and maintaining healthcare coverage and adequate reimbursement from third- party payors; • qualifying for, maintaining, enforcing, and defending intellectual property rights and claims; and • the risk that foreign regulatory authorities may not authorize our clinical trial protocols and other clinical trial documentation, including manufacturing documentation, even when previously authorized by the FDA, EMA or MHRA, which could lead to a delay in starting such clinical trials. For example, our HBV002 clinical trial conducted in South Korea experienced delays due to additional regulatory review of our clinical protocol. We have limited experience obtaining such approvals in foreign jurisdictions and therefore may need more time to navigate the regulatory process as a result. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. We have no control over third- party use of ChAdOx and MVA technologies outside of our exclusively licensed field under license from OUI, and such third- party use could have a negative impact on our ability to **partner or** develop current and future product candidates, which would materially harm our business. Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If our preclinical studies and clinical trials are not sufficient to support marketing authorization of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate. We may experience delays in obtaining the FDA' s or other regulatory agencies authorization to initiate clinical trials under future INDs, completing ongoing preclinical studies of our other product candidates, and initiating our planned preclinical studies and clinical trials. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of participants on time, or be completed on schedule, if at all. We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive marketing authorization or commercialize our product candidates, including: • we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; • new treatments may become standard of care during the process of completing a clinical trial, which may impact the initial clinical trial design or future patient care pathways; • significant changes in relevant regulatory requirements may cause a delay in the start of a clinical trial, due to additional requirements needing to be met; • clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other product candidates; • clinical trials of our product candidates may not produce differentiated or clinically significant results across ~~infectious~~ **the** ~~diseases~~ - **disease** ~~, cancers and autoimmune diseases~~ **areas that we focus on** ; • the number of participants required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate; • our third- party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient or timely product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all; • we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non- compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks; • the cost of clinical trials of our product candidates may be greater than we anticipate, for example, if we experience delays or challenges in identifying participants with the eligibility criteria required for our clinical trials, we may have to reimburse sites for the cost of testing of additional participants in order to encourage enrollment of additional participants; • the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes; • regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and • future collaborators may conduct clinical trials in ways they view as

advantageous to them but that are suboptimal for us. In addition, the ChAdOx vectors are currently being evaluated in clinical trials outside of our licensed fields conducted by Oxford and other third parties to which OUI has granted licenses. We have no control over these other clinical trials and any adverse results in these clinical trials could impact public perception and regulatory approval of our product candidates. Even after any of our product candidates obtain regulatory marketing authorization, the announcement of adverse events observed in individuals who receive these products may impact public perception and may result in increased regulatory scrutiny across our platform. For example, in March 2021, several countries announced plans to either temporarily suspend the use of a particular batch of Vaxzevria or the use of Vaxzevria altogether following reports of very rare thromboembolic events in people following vaccination. While the EMA subsequently issued an update confirming the overall risk- benefit profile of Vaxzevria remains positive, and Vaxzevria later received full marketing authorization in the EU in November 2022, ~~the applicable regulatory authorities continue to assess available safety data as Vaxzevria continues to be administered and have made recommendations regarding updates to the vaccine' s labeling and use in certain populations. These recommendations may continue to evolve, and~~ these types of announcements may affect public perception of the safety of Vaxzevria, which may extend to product candidates we are developing. Other very rare events have been reported in people who have received Vaxzevria, including thrombocytopenia (low platelet numbers in the blood), capillary leak syndrome, and neurological syndromes such as Guillain Barre Syndrome and transverse myelitis. Perception about the efficacy of Vaxzevria, such as its effectiveness against emerging COVID- 19 variants, may also impact perception of our **other** product candidates. Additionally, these announcements may lead to additional inquiries or scrutiny from regulators on whether similar safety or efficacy signals have been observed with our other candidates. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs, or ethics committees of the institutions in which such clinical trials are being conducted, or by the FDA or other regulatory authorities, or suspended or terminated based on recommendations by the Data Safety Monitoring Board or equivalent for such clinical trial. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, any disclosure of negative data of clinical trials being conducted by our collaborators could have an adverse impact on our business. Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the clinical trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. If we experience delays in the completion of any preclinical study or clinical trial of our product candidates, or our preclinical studies or clinical trials are terminated, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and authorization procedure and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing authorization for our product candidates. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, **this** ~~our entire pipeline may have little, if any, value, which~~ would have a material and adverse effect on our business, financial condition, results of operations and prospects. Interim, " topline, " and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data ~~become~~ **becomes** available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or **"** topline **"** data from our preclinical studies and clinical trials, which ~~is~~ **are** based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change **,** following a more comprehensive review of the more complete data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies or clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data ~~are~~ **is** available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by

us or by our competitors could result in volatility in the price of our ADSs. In addition, the ChAdOx vectors are currently being evaluated in clinical trials conducted by Oxford **University / OUI** and other third parties to which Oxford **University / OUI** has granted licenses. We have no control over these other clinical trials and any adverse results in these clinical trials could impact public perception and regulatory approval of our product candidates. The information these third parties choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and shareholders may not agree with what these third parties determine is material or otherwise appropriate information to include in their disclosure. Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and shareholders may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from more complete results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain marketing authorization for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Our product candidates are based on a novel approach to the treatment of infectious disease ~~,~~ **and** autoimmunity ~~and cancer~~ , which makes it difficult to predict the time and cost of product candidate development. We have concentrated our research and development efforts on components of our proprietary platforms to develop product candidates that **either** stimulate powerful, targeted immune responses against pathogens ~~and tumor cells~~ **or promote immune tolerance for suppressing unwanted inflammation** , which **are** ~~is a~~ novel ~~approach~~ **approaches** . Our future success depends on the successful development of these platforms. There can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA or foreign regulatory authorities may refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing other testing and manufacturing methods, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of novel immunotherapies. Any novel immunotherapies that are approved may be subject to extensive post- approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements. Difficulty in enrolling participants could delay or prevent clinical trials of our product candidates and prevent us from realizing the full commercial potential of any products we may develop. Identifying and qualifying participants to participate in clinical trials of our product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit participants to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible participants to participate in these trials as required by the FDA, the EMA or other foreign regulatory authorities ~~. For example, randomized clinical controlled trials for MERS are difficult due to the sporadic and low incidence of cases. Our ability to enroll participants may be significantly delayed when potential participants for our clinical trials have had previous exposure to the ChAdOx1 vector, as we may not be able to enroll these individuals in a clinical trial or their enrollment may be delayed due to the concern that neutralizing antibodies might be present for some time after ChAdOx exposure. For example, we may not be able to enroll or may need to delay the enrollment of potential subjects who received the Vaxzevria vaccine. Although we believe the presence and impact of such neutralizing antibodies is transient, we do not have full data on this yet and our assessment may change. The initiation of our Phase 1 / 2a clinical trial for VTP- 200, our Phase 1b / 2a clinical trial for VTP- 300 and our Phase 1 / 2a clinical trial for VTP- 600, were delayed due to COVID- 19~~ . We cannot anticipate the next pandemic or how that may or may not impact future clinical trial enrollment. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and participants who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. The enrollment of patients and participants further depends on many factors, including: • the phase of clinical testing; • the proximity of participants to clinical trial sites; • the increased inconvenience to patients by participating in a clinical trial, such as increased doctor visits, missed work, travel costs and time; • the design of the clinical trial, including the number of site visits, whether the clinical trial includes a placebo arm and invasive assessments required; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • our ability to obtain and maintain participant consents; • reporting of the preliminary results of any of our clinical trials; • the risk that some or all of the patients that receive Vaxzevria develop neutralizing antibodies against ChAdOx, which could limit the immunogenicity from subsequent dosing with one of our product candidates **that utilize ChAdOx** ; • the risk that participants enrolled in clinical trials will drop out of the clinical trials before clinical trial completion; and • factors we may not be able to control, such as potential pandemics that may limit participants, principal investigators or staff or clinical site availability ~~(e. g., the COVID- 19 pandemic)~~ . Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of participants who are available for our clinical trials at such

clinical trial sites. Moreover, because certain of our product candidates represent a departure from more commonly used methods for treatment of disease ~~, particularly in cancer~~, and because certain of our product candidates have not been tested in humans before, potential participants and their doctors may be inclined to use conventional therapies, rather than enroll participants in a future clinical trial. If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. Our product candidates may cause serious adverse events, serious side effects or have other properties that could halt their clinical development, prevent their marketing authorization, require expansion of the trial size, limit their commercial potential or result in significant negative consequences. Serious side effects caused by our product candidates could cause us or regulatory authorities, including IRBs and ethics committees, to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing authorization by the FDA, the EMA or other comparable foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. Because of our dose escalation design for our clinical trials, undesirable side effects in initial cohorts could also result in the need to expand the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, because certain of our product candidates, including Vaxzevria, have been administered to substantial numbers of participants on a more rapid basis than is standard in clinical trials, undesirable side effects could result in a negative impact across a larger participant population. Results of our **clinical** trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. If we do observe serious side effects in our clinical trials, our ongoing clinical trials may be halted or put on clinical hold prior to completion if there is an unacceptable safety risk for participants. If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the EMA or other comparable foreign regulatory authorities, or local regulatory authorities such as IRBs or ethics committees, could order us to cease clinical trials. Competent national health authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications **and if an approval is granted for an indication, the regulatory authority may require us to include a warning in the patient information leaflet** . Even if the side effects presented do not preclude the product from obtaining or maintaining marketing authorization, treatment- related side effects could also affect participant recruitment **for a clinical trial,** or the ability of enrolled participants to complete ~~the~~ **their participation in a clinical** trial or result in potential product liability claims **, particularly if they have not been described in the patient information leaflet** . In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We intend to develop certain of our product candidates in combination with other therapies, which exposes us to additional risks. We intend to develop certain of our product candidates in combination with one or more other approved therapies, such as anti- PD- 1 antibodies and other checkpoint inhibitors to treat certain cancers and ~~chronic infections~~ **infectious diseases** . Even if any product candidate we develop were to receive marketing authorization or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, the EMA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, the EMA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. We also may choose to evaluate our current product candidates and any other future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, the EMA or comparable foreign regulatory authorities. We will not be able to market and sell our current product candidates or any product candidate we develop in combination with any unapproved therapies for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. If the FDA, the EMA or comparable foreign regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the products we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy. Risks Related to Our Approach The market opportunities for certain of our ~~oncology~~ product candidates may be relatively small as it may be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate. ~~Cancer therapies~~ **Immunotherapies for treating patients with autoimmune and other inflammatory diseases** are sometimes **staged based on disease severity or may be** characterized by line of therapy (first line, second line, third line, fourth line, etc.), and the regulatory authorities, including the FDA, often approve new therapies initially only for a particular line or lines of use. **Our product candidates based on SNAP- TI are at early stages of development and there is currently uncertainty as to how the may fit into existing treatment paradigms. We expect to seek approval of VTP- 1000 as a first line therapy but for our other SNAP- TI product candidates we may need to seek approval for use as a second or later line of therapy or in patients who do not respond to more conservative management. Similarly, cancer therapies are sometimes characterized by line of therapy (first line, second line, third line, fourth line, etc.), and the regulatory authorities, including the FDA, often approve new therapies initially only for a particular line or lines of use.** When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor- targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor- targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor- targeted therapies, more

invasive forms of surgery and new technologies. We expect to **advance** ~~seek approval of~~ VTP- 600 as a component of first line therapy but we expect to **advance** ~~seek approval of~~ our other oncology product candidates initially as second or third line therapy, for use in patients with relapsed or refractory metastatic cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial as third line or second line therapies, if any, we would expect to **advance** ~~seek approval~~ as earlier line therapies, but there is no guarantee that our product candidates, even if approved as a second or third line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. Our projections of both the number of people who have the ~~infectious diseases~~ - **disease that** ~~and cancers~~ we are targeting, as well as the subset of people with these **conditions** ~~infectious diseases and cancers~~ in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, commissioned reports, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of these **conditions** ~~cancers and chronic infections~~. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates within our addressable patient population, because the potential target populations are small, we may never achieve profitability without obtaining marketing authorization for additional indications, including use as first or second line therapy. Negative developments in the ~~fields~~ - **field** of **immunotherapeutics** ~~infectious disease and immuno- oncology~~ could damage public perception of any of our product candidates and negatively affect our business. The commercial success of our product candidates will depend in part on public acceptance of the use of immunotherapies and viral vector- based antigen-delivery platforms. Adverse events in clinical trials of VTP- **1000** ~~300 and VTP- 200~~, or in clinical trials of similar products developed by others and the resulting publicity, as well as any other negative developments in the field of **immunotherapeutics** ~~infectious disease and immuno- oncology~~ that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for any product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of ~~cancer~~ immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial participants may be discouraged from enrolling in our clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain marketing authorization or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, prospects and results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs. ~~Our present~~ **Several of our product candidates utilize SNAP- TI to induce immune tolerance. Adverse developments in clinical trials of other immunotherapy products that promote antigen- specific immune tolerance, may result in a disproportionately negative effect for our platform, as compared to other products within the I & I field that do not rely on antigen- specific immune tolerance. Future negative developments in the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates. Several of our** product candidates consist of modified viruses. Adverse developments in clinical trials of other immunotherapy products based on viruses, ~~such as oncolytic viruses,~~ may result in a disproportionately negative effect for our platform as compared to other products ~~in the field of infectious disease and immuno- oncology~~ that are not based on viruses. Future negative developments in the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates. We may not be successful in our efforts to identify and successfully commercialize additional product candidates. Part of our strategy involves researching and developing novel product candidates. We have developed a pipeline of product candidates and intend to pursue clinical development of additional product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also: • we may not be able to assemble sufficient resources to acquire or discover additional product candidates; • competitors may develop alternatives that render our potential product candidates obsolete or less attractive; • potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights; • potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance; • potential product candidates may not be effective in treating their targeted diseases or symptoms; • the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable; • a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or • the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically. Developing, obtaining marketing authorization for and commercializing additional product candidates will require substantial additional funding and is prone to the risks of failure inherent in **all** ~~medical~~ **medicinal** product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process **, which is a risk that applies to all medicinal product development**. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. We may choose to focus our efforts on and allocate resources to a potential product candidate that

ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products **because of the risks inherent in conducting clinical trials** . If we are unable to evaluate the commercial potential or target market for a particular product candidate, identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position. Risks Related to Sales, Marketing and Competition We face substantial competition in an environment of rapid technological change, which may result in others discovering, developing, obtaining marketing authorization approval or commercializing products before or more successfully than we do, which may adversely affect our financial condition and our ability to successfully market or commercialize our product candidates. The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our scientific knowledge, platform technology and development expertise provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, as well as public and private research institutes that conduct research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, marketing authorizations and product marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting **milestone payments and** royalties for use of technology that they have developed. Our competitors may compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and participant registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do. Product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Specifically, we expect that our product candidates **based on SNAP- TI will compete against alternative or more conventional approaches, including anti- inflammatory compounds, monoclonal antibodies against cytokines or other pathways, immune cell depletion regimens (e. g., antibodies, CAR- T cells and T cell engagers) immunomodulatory small molecules, transgenic T cells, genetic therapies and other antigen- specific immune tolerance therapies based on proteins, DNA, RNA and peptides or other technologies. We expect that our product candidates based on our viral vector platforms** will compete against alternative or more conventional approaches, including antivirals, immune modulators, antisense oligonucleotides, siRNA, CRISPR editing, capsid inhibitors, novel entry inhibitors, or other small molecules, RNA, DNA, nanoparticle, VLP, peptide, protein, whole- killed vaccines or other technologies. If our product candidates are approved for the indications for which we are currently conducting or planning clinical trials, they will likely compete with the competitor products mentioned above and with other products that are currently in development. Key product features that would affect our ability to effectively compete with other therapeutics include the safety, efficacy, formulation, stability, and convenience of our products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The availability of reimbursement from government and other third- party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain marketing authorizations from the FDA or other regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Risks Related to the Development of Our Product Candidates Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, potency, purity, and efficacy of any of our product candidates, which would prevent or delay development, marketing authorization and commercialization. Furthermore, success in preclinical studies or clinical trials may not be indicative of results in future clinical trials for the same or other product candidates. Before obtaining marketing authorization for the commercial sale of our product candidates, we must demonstrate the safety, purity and potency of our investigational biologics **and drugs** for use in each target indication through lengthy, complex and expensive preclinical studies and clinical trials. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict human experience. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired risk- benefit profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller- scale clinical trials may not be predictive of eventual safety or effectiveness in large- scale pivotal clinical trials. **For example,** VTP- 100 demonstrated tolerability and immunogenicity during small Phase 1 clinical trials but did not demonstrate sufficient clinical activity during adequately powered Phase 2b clinical trials to warrant continued development of this product candidate. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later phase clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. The vast majority of product candidates that commence preclinical studies and early phase clinical trials

are never approved as products. Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency, purity and efficacy necessary to obtain regulatory authorization to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, potency, purity, and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing authorization for certain of our product candidates. In some instances, there can be significant variability in safety, potency, purity, or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. **As** ~~While we have not yet initiated clinical trials for certain of our product candidates, such as VTP- 1000, and are in early stages of clinical trials for certain of our product candidates, VTP- 300, VTP- 500, VTP- 200, VTP- 400, VTP- 850 and VTP- 600, as~~ is the case with all **investigational biologics and drugs, including** novel immunotherapeutics ~~and~~ **such as those based on our** viral **vector and SNAP** - **TI** ~~vector based antigen- delivery~~ platforms, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny authorization of certain of our product candidates for any or all targeted indications. Treatment- related side effects could also affect participant recruitment or the ability of enrolled participants to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, some of the clinical trials we conduct may be open- label in trial design and may be conducted at a limited number of clinical sites on a limited number of patients. An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open- label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open- label clinical trial when studied in a controlled environment with a placebo or active control. Even if we obtain marketing authorization for our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community. The use of novel immunotherapeutics, ~~nanoparticle~~ **such as our SNAP- TI** and viral- vector based product candidates to target the treatment and prevention of ~~infectious diseases, and cancer and~~ autoimmune diseases **, infectious disease and cancer** is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including: • the clinical indications for which our product candidates are licensed; • physicians, hospitals ~~, cancer treatment centers~~ and patients considering our product candidates as a safe and effective treatment; • the potential and perceived advantages of our product candidates over alternative treatments, including the adoption of our treatment as the standard of care; • our ability to demonstrate the advantages of our product candidates over other ~~vaccines and cancer, or chronic infectious disease or immune tolerance disease~~ medicines; • the prevalence and severity of any side effects; • the prevalence and severity of any side effects for other immunotherapeutics and public perception of other immunotherapeutics; • the prevalence and severity of any side effects for other viral- vector based antigen- delivery platforms and public perception of other viral- vector based antigen- delivery platforms; • ~~The~~ **the** prevalence and severity of any side effects for other nanoparticle- based therapeutics and public perception of other nanoparticle- based therapeutics **; • the prevalence and severity of any side effects for other antigen- specific immune tolerance therapies or those utilizing rapamycin and public perception of other antigen- specific immune tolerance therapies and those utilizing rapamycin;** • product labeling or product insert requirements of the FDA or other regulatory authorities; • limitations or warnings contained in the approved labeling; • the timing of market introduction of our product candidates as well as competitive products; • the cost of treatment in relation to alternative treatments; • the availability of adequate coverage, reimbursement and pricing by third- party payors and government authorities; • the willingness of patients to pay out- of- pocket in the absence of coverage by third- party payors and government authorities; • relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and • the effectiveness of our sales and marketing efforts. If our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals ~~, cancer treatment centers~~ or others in the medical community, we will not be able to generate significant revenue. In addition, although our product candidates differ in certain ways from other immunotherapeutic ~~and viral- vector~~ based approaches, serious adverse events or deaths in other clinical trials involving immunotherapeutic ~~and viral- vector~~ based product candidates, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete. We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be

able to generate product revenue. We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in- house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time- consuming and could delay any product launch. If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third- party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third- party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in- house sales and distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product in the United States or overseas. Insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, umbrella, and directors' and officers' insurance. Insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or marketing authorizations could be suspended. We ~~also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We~~ do not know ~~, however,~~ if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. Risks Related to Our Reliance on Third Parties We rely, and expect to continue to rely, on third parties to conduct certain of our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain marketing authorizations for, or commercialize, our product candidates and our business could be substantially harmed. We utilize and depend, and expect to continue to utilize and depend, upon independent investigators and collaborators, such as medical institutions, contract research organizations (" CROs"), contract manufacturing organizations (" CMOs"), and strategic partners to conduct and support certain of our preclinical studies and clinical trials under agreements with us ~~. For example, we are dependent on our regional partner, CanSino Biologics, to conduct a Phase 1 clinical trial of VTP- 400 for herpes zoster prevention~~ . We expect to have to continue to negotiate budgets and contracts with CROs, trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we, or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our MMAs. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test participants. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of participants may require us to repeat clinical trials, which would delay the marketing authorization process. Moreover, our business may be implicated if any of these third parties performing services or otherwise acting on our behalf violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or

regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain marketing authorization for, or successfully commercialize, our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. We may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements. We may form or seek additional strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency, purity, and efficacy and obtain marketing approval. Further, collaborations involving our product candidates are subject to numerous risks, which may include the following: • collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration; • collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • despite agreements, collaborators may develop our product candidates to standards that only meet their local regulatory requirements and therefore clinical data cannot be applied in support regulatory submissions in other jurisdictions; • collaborators in certain countries may require joint ventures to ~~manufactures~~ **manufacture** and commercialize products in their territory, which may increase costs, increase dilution to shareholders, and offer lack of clarity on revenue and intellectual property sharing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates; • a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution; • collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; • disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources; • collaboration and grant funding agreements may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and • collaborators may own or co- own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property. As a result, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations. We currently rely and expect to rely in the future on the use of manufacturing suites in third- party facilities or third parties to manufacture our product candidates, if approved. Our business could be harmed if we are unable to use third- party manufacturing suites or if the third party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices. We do not currently own any facility that may be used as our clinical- scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms. We have not yet manufactured our product candidates on a commercial scale and may not be able to do so for any of our product candidates. Manufacturing of biologic and synthetic products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up, validating the production process and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including lot consistency, stability of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Our anticipated reliance

on a limited number of third- party manufacturers exposes us to a number of risks, including the following: • the production process for our product candidates is complex and requires specific know- how that only a limited number of CMOs can provide, as a result, we compete with other companies in the field for the scarce capacities of these organizations and may not be able to secure sufficient manufacturing capacity when needed; • we may be unable to identify manufacturers on acceptable terms, or at all because the number of potential manufacturers is limited and the FDA or other regulatory authorities may inspect any manufacturers for current cGMP compliance as part of our marketing application; • a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates; • our third- party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any; • contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately; • our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products, if any; • manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards and we have no control over third- party manufacturers' compliance with these regulations and standards; • we may not own, or may have to share, the intellectual property rights to any improvements made by our third- party manufacturers in the manufacturing process for our product candidates; • our third- party manufacturers could breach or terminate their agreements with us; • our third- party manufacturers may prioritize another customer' s needs in front of ours, especially in the event of a global pandemic; • raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects, may be in short supply, and may significantly increase in price; • our contract manufacturers and critical suppliers may be subject to inclement weather, pandemics, as well as natural or man- made disasters; and • our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. **Regional or single- source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances we, our collaborators or other third parties on which we rely, depend on China- based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China- based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or if the previously proposed federal legislation known as the BIOSECURE Act or a similar law were to be enacted.** Additionally, if any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial distribution could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, in the case of the CMOs that supply our product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging or comparability studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, EMA or other appropriate regulatory authorities and result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA, or other regulatory authorities could place significant restrictions on our company until deficiencies are remedied. Our manufacturing process needs to comply with FDA and comparable foreign regulatory authority regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any marketing authorizations. In order to commercially produce our products either at our own facility or at a third party' s facility, we will need to comply with the FDA' s cGMP regulations and guidelines and similar requirements from comparable foreign regulatory authorities. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of our biologic products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory

requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our biological products for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non- compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business. If our third- party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including biological materials, by our third- party manufacturers. Our manufacturers are subject to national, state, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing, and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or national authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. Risks Related to Government Regulation The marketing authorization processes of the FDA, the EMA, MHRA and other comparable foreign regulatory authorities are lengthy, time- consuming, and inherently unpredictable, and if we are ultimately unable to obtain marketing authorizations for our product candidates, or the marketing authorization is for a narrower indication than we seek, our business will be substantially harmed. The time required to obtain marketing approval from the FDA, the EMA, MHRA and other comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. We have not yet obtained a marketing authorization for any product candidate and it is possible that none of our current or future product candidates will ever obtain marketing authorizations. Our current and future product candidates could fail to receive marketing authorizations for many reasons, including the following: • the availability of financial resources to commence and complete planned clinical trials; • the FDA, the EMA, MHRA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a ~~Biologics Licensing Application (" BLA ")~~ **or NDA** to the FDA, or an MAA to the EMA or other comparable submission to regulatory authorities in other regions, to obtain authorization in the United States, the European Union, or elsewhere; • we may be unable to demonstrate to the satisfaction of the FDA, the EMA, MHRA or regulatory authorities in other regions that a product candidate has an overall suitable benefit / risk profile for its proposed indication; • the FDA, the EMA, MHRA or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; • **Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. •** the approval policies or regulations of the FDA, the EMA, MHRA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and • the risk that foreign regulatory authorities may not authorize our clinical trial protocols and other clinical trial documentation, including manufacturing documentation, even when previously authorized by the FDA, EMA or MHRA, which could lead to a delay in starting such clinical trials. For example, the conduct of our HBV002 clinical trial in South Korea experienced delays due to additional regulatory review of our clinical protocol. We have limited experience obtaining such approvals in foreign jurisdictions and therefore may need more time to navigate the regulatory process as a result. The unpredictability of clinical trial results may result in our failing to obtain marketing authorizations for any product candidate we develop, which would significantly harm our business, results of operations and prospects. The lengthy approval process in many regions may cause delays in market access, particularly if regulatory authorities have a large number of objections to the initial applications for marketing authorization which need to be addressed. We have conducted, and intend to conduct, clinical trials of certain of our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data are subject to certain conditions imposed by the FDA, including compliance with all applicable U. S. laws and regulations. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCP, including review and approval by an independent ethics committee and informed consent from participants. The trial population must also adequately represent the U. S. population, and the data must be applicable to the U. S. population and U. S. medical practice in ways that the FDA deems clinically meaningful. In general, the participant population for any clinical ~~trials~~ **trial** conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. There can be no assurance the FDA will accept data from trials conducted outside of the United States. The FDA, the EMA and other comparable foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether marketing authorization will be obtained for any product candidate that we develop. **For example,** ~~Even~~ **even** if we believe the data

collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA, MHRA or any other comparable foreign regulatory authorities. **In addition, U. S. Supreme Court' s July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA' s regulations, policies and decisions may become subject to increasing legal challenges, delays, and / or changes.** Even if we were to obtain **a** marketing authorization, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval conditional on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. We may seek Orphan Drug Designation for drug candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity. In addition, even if we obtain orphan drug exclusivity for any of our product candidates, such exclusivity may not protect us from competition. As part of our business strategy, we may seek Orphan Drug Designation for any drug candidates we develop, and we may be unsuccessful in obtaining such designation. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. Similarly, in the EU, the European Commission grants designation after receiving the opinion of the Committee for Orphan Medicinal Products on a designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life- threatening or chronically debilitating conditions affecting not more than five in 10, 000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life- threatening, seriously debilitating, or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor. Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified. Even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the drug candidate from competition because different therapies can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve ~~the same~~ **a second** drug **candidate** for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure **manufacture of** sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug candidate nor gives the drug candidate any advantage in the regulatory review or approval process. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. While we may seek Orphan Drug Designation for applicable indications for our current and any future drug candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations. A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek Breakthrough Therapy designation for certain of our current and future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, defined as those that measure an effect on irreversible morbidity or mortality or on symptoms that represent serious consequences of the disease. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to

make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for certain of our current and future product candidates for the treatment and prevention of infectious diseases and cancer, there can be no assurance that we will receive breakthrough therapy designation. A Fast Track designation by the FDA, even if granted for certain of our current or future product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval. If a drug or biologic is intended for the treatment of a serious or life- threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for certain of our current or future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time. Accelerated approval by the FDA, even if granted for certain of our current or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek approval of certain of our current or future product candidates using the FDA' s accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life- threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well- controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors must also update FDA on the status of these studies, and under FDORA, the FDA has increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post- approval studies fail to verify the drug' s predicted clinical benefit. In addition, the FDA currently requires sponsors, unless otherwise informed by the agency, to request pre- approval of promotional materials for products receiving Accelerated Approval, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval. If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway. The Patient Protection and Affordable Care Act, as amended by the ACA, includes a subtitle called the BPCIA which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA- licensed reference biologic product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity, and potency of the other company' s product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12 year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Even if we obtain FDA, ~~EMA~~ **European Commission** or MHRA approval for our current or future product candidates that we may identify and pursue in the United States, **the** ~~Europe~~ **European Union** or the United Kingdom, we may never obtain approval to commercialize any such product candidates outside of those jurisdictions, including in Asian markets wherein we intend to commercialize VTP- 300, which would limit our ability to realize their full market potential. Obtaining and maintaining marketing authorization for our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing authorizations in any other jurisdiction, while a failure or delay in obtaining marketing authorization in one jurisdiction may have a negative effect on the approval process in others. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Approval processes vary among countries and can involve additional product

testing and validation and additional or different administrative review periods 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. Seeking foreign marketing authorization could result in difficulties and costs and require additional preclinical studies or clinical trials which could be costly and time- consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our current or future product candidates in those countries. The foreign marketing authorization process may include all of the risks associated with obtaining FDA, ~~EMA~~ **European Commission** or MHRA approval, in addition to country- specific risks and challenges. For example, we are **looking to partner the further** ~~developing~~ **development of** VTP- 300 for chronic hepatitis B, which is **a condition** most prevalent in China and other countries in Asia. We have limited development experience in this market and we may need to rely on a local, third- party partner to help us navigate the applicable regulatory requirements. Additionally, governments in this target market may deem the eradication of HBV infections to be a national priority which could impact the framework for available reimbursement or our ability to achieve a standard commercial return based on the value of our product, if approved. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining marketing authorizations in international markets for our current or future product candidates. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if marketing authorization in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our current or future product candidates will be harmed. Future changes to tax laws could materially adversely affect our financial condition and results of operations, and reduce net returns to our shareholders. We conduct business globally and file tax returns in multiple jurisdictions. The tax treatment of the Company or any of the group companies could be materially adversely affected by several factors, including: changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms under consideration (such as those related to the Organization for Economic Co- Operation and Development' s Base Erosion and Profit Shifting Project, the European Commission' s state aid investigations and other initiatives); the practices of tax authorities in jurisdictions in which we operate; the resolution of issues arising from tax audits or examinations and any related interest or penalties. Such changes (which may be retroactive) may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices in jurisdictions in which we operate, could affect our financial position, future results of operations, cash flows in a particular period and overall or effective tax rates in the future in countries where we have operations, reduce post- tax returns to our shareholders and increase the complexity, burden and cost of tax compliance. Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes or non- realization of expected benefits. We operate in a number of countries throughout the world. Consequently, we are subject to tax laws, treaties, and regulations in the countries in which we operate, and these laws and treaties are subject to interpretation. We have taken, and will continue to take, tax positions based on our interpretation of such tax laws. A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example HMRC, the IRS or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. There can be no assurance that a taxing authority will not have a different interpretation of applicable law and assess us with additional taxes. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a " permanent establishment " under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material tax liabilities, interest and penalties are payable by us, for example where there has been a technical violation of contradictory laws and regulations that are relatively new and have not been subject to extensive review or interpretation, in which case we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable, or result in other liabilities. If we are assessed with additional taxes, this may result in a material adverse effect on our results of operations and / or financial condition. We may be unable to use net operating loss and tax credit carryforwards and certain built- in losses or tax credits to reduce future tax payments or to benefit from favorable U. K. tax legislation. **Our** ~~As a~~ U. K. incorporated and tax resident **entities** ~~entity, we~~ are subject to U. K. ~~corporate~~ **corporation** ~~taxation~~ **tax** . Due to the nature of our business, we have generated losses since inception and therefore have not paid any U. K. corporation tax. As of December 31, ~~2023~~ **2024** , we had cumulative carryforward tax losses of approximately $ ~~92~~ **101** . 7 million (December 31, ~~2022~~ **2023** : $ ~~39~~ **92** . ~~6~~ **7** million). Subject to any relevant criteria and restrictions (including those that limit the percentage of profits that can be reduced by carried forward losses and those that can restrict the use of carried forward losses where there is a change of ownership of more than half of our ordinary shares and a major change in the nature, conduct or scale of the trade), we expect these to be eligible for carry forward and utilization against future operating profits, if any. The use of loss carryforwards in relation to U. K. profits incurred on or after April 1, 2017 is generally limited each year to £ 5. 0 million plus an incremental 50 % of U. K. taxable profits. As a company that carries out extensive research and development activities, we seek to benefit from the U. K. research and development tax relief programs, being the Small and Medium- sized Enterprises R & D tax relief program, or SME Program, and, to the extent that our projects are grant funded or relate to work subcontracted to us by third parties, the Research and Development Expenditure Credit program. Under the SME Program, where available, we may be able to surrender some of

our trading losses that arise from our qualifying research and development activities for cash or carry forward such losses for potential offset against future profits (subject to relevant restrictions). The majority of our research, clinical trials management and manufacturing development activities are eligible for inclusion within these tax credit cash rebate claims. Our eligibility to claim payable research and development tax credits may be limited or eliminated because we may no longer qualify as a small or medium- sized company. In addition, the SME Program has been amended by the Finance Act 2021 which came into force in April 2021. This legislation introduced a cap on claims under the SME Program to a multiple of payroll taxes (broadly, to a maximum payable credit equal to £ 20, 000 plus three times the total PAYE and NICs liability of the company) subject to an exception which prevents the cap from applying. That exception requires the company to be creating, taking steps to create or managing intellectual property, as well as having qualifying research and development expenditure in respect of connected parties which does not exceed 15 % of the total claimed. If such exception does not apply, this could restrict the amount of payable credit that we claim. **There was no tax loss restriction applied to the R & D tax credits in the U. K. for the years ending December 31, 2024 and 2023.** Changes to the U. K. R & D tax relief legislation that have been recently enacted ~~or proposed~~ , and which took effect from April 2023, reduce the R & D cash rebate rate under the SME Program **. For expenditure incurred on or after April 1** , ~~and may introduce~~ **2024, there are** restrictions on relief that may be claimed for expenditure on sub- contracted R & D activity, broadly requiring either that workers carrying on such activity are subject to U. K. PAYE or, where work is undertaken outside the U. K., that this must be due to geographical, environmental, social or other conditions that: (i) are not present in the U. K.; and (ii) it would be wholly unreasonable to replicate in the U. K. ~~This~~ **These** rate ~~reduction~~ **reductions** and ~~any proposed~~ restrictions ~~may~~ impact the quantum of R & D relief that we are able to claim ~~in the future~~ . In addition, ~~the U. K. government is currently consulting on the potential replacement of the SME Program and RDEC Program with a single program, operating similarly to the RDEC Program, which may, inter alia, change the present treatment of sub- contracted R & D work and introduce different thresholds and caps on expenditure and relief. If enacted, the new program would be expected to have effect for expenditure incurred from April 2024 onwards, and could have a material impact on the quantum of R & D relief that we are eligible to claim. This~~ **this** ~~announcement~~ **legislation** also saw the introduction of a higher rate of relief for loss- making R & D- intensive small and medium enterprises, the SME Intensive Scheme. Companies claiming under the existing SME Intensive Scheme tax relief will be eligible for a higher payable credit rate if they meet the definition for R & D intensity. ~~We will assess if~~ **From the analysis performed,** we ~~can~~ **have not and do not currently expect to** claim under the ~~new~~ loss- making R & D ~~- intensive SME~~ Intensive Scheme for ~~the accounting period ending December 31, 2024 and future periods, which will provide benefits consistent with those claimed under the current SME~~ **SMEs** ~~Programs~~ **primarily due to the proportion of total relevant expenditure occurring outside the United Kingdom** . We may benefit in the future from the U. K.' s " patent box " regime, which allows certain profits attributable to revenue from patented products (and other qualifying income) to be taxed at an effective rate of 10 % by giving an additional tax deduction. When taken in combination with the enhanced relief available on our research and development expenditures, we expect a long- term effective rate of corporation tax lower than the statutory rate to apply to us. If, however, there are unexpected adverse changes to the U. K. R & D tax credit regime or the " patent box " regime, or for any reason we are unable to qualify for such advantageous tax legislation, or we are unable to use net operating loss and tax credit carryforwards and certain built- in losses to reduce future tax payments then our business, results of operations and financial condition may be adversely affected. This may impact our ongoing requirement for investment and the timeframes within which additional investment is required. For completeness, it should be noted that the ~~UK~~ **U. K.** tax authority, **His Majesty' s Revenue and Customs ("** HMRC **")** , currently has an increased focus on claims for R & D tax credits and so the Company may be subject to increased scrutiny in respect of any claims it makes. In addition, the legislation on the ~~UK~~ **U. K.** R & D tax credits regime is updated and changed frequently, so there can be no guarantee of our ability of to make use of such credits as we might currently expect to in future. Risks Related to Ongoing Regulatory Obligations Even if we receive marketing authorization for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. Any marketing authorizations that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS and the EMA may also require additional rapid microbiological method approvals or educational materials in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMPs, good laboratory practice regulations and GCPs, for any clinical trials that we conduct post- approval, and compliance with applicable product tracking and tracing requirements. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls; • manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation; • revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings; • imposition of a REMS, which may include distribution or use restrictions; • requirements to conduct additional post- market clinical trials to assess the safety of the product; • fines, warning letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or

suspension or revocation of approvals; • product seizure or detention, or refusal to permit the import or export of our product candidates; and • injunctions or the imposition of civil, criminal, or administrative penalties. Additionally, under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product' s ability to be marketed. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing authorization of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. The FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses. If any of our product candidates are approved and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product' s approved labeling. If we are found to have promoted such off- label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. The insurance coverage and reimbursement status of newly-approved products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for any of our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors and, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our or their commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval. See section entitled " Business – Government Regulation – Coverage and Reimbursement. " Our ability to successfully commercialize our product candidates or any other products that we or they may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payors. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs and commercial payors are critical to new product acceptance. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and other third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe and certain other major markets where we plan to commercialize may put pressure on the pricing and usage

of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems, and pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, efforts by governmental and other third- party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. Many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. As a result, increasingly high barriers are being erected to the entry of new products. Healthcare legislative or regulatory reform measures may have a material adverse effect on our business and results of operations. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in applicable laws, rules, and regulations or the interpretation of existing laws, rules, and regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. See the section entitled " Business – Government Regulation – Healthcare Reform and Legislative Changes. " We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product candidate. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be modified or invalidated. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs, and could have a material adverse effect on our business, financial condition, and results of operations. Our business activities will be subject to the Foreign Corrupt Practices Act (" FCPA"), and similar anti- bribery and anti- corruption laws in other jurisdictions. As we engage in and expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or the SEC, and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition. ~~Inadequate~~ **Currently, federal agencies in the U. S. are operating under a continuing resolution that is set to expire on September 30, 2025. Without appropriation of additional** funding **to federal agencies, our business operations related to our product development activities** for the **U. S. market** ~~FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations,~~ could **be** ~~hinder their ability to hire and retain~~

~~key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact~~ **impacted** ~~our business~~. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. For example, over the last several years the U. S. government has shut down several times and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Our business operations and current and future relationships with principal investigators, healthcare providers, including physicians, consultants, third- party payors and customers may be subject, directly or indirectly, to U. S. federal and state, as well as foreign, healthcare fraud and abuse laws, false claims laws, health information privacy and ~~security~~ **cybersecurity** laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers, including physicians and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors subject us to various U. S. federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the AKS, the federal civil and criminal false claims laws, and the law commonly referred to as the Sunshine Act, along with regulations promulgated under such laws. These laws impact, among other things, our clinical research activities, proposed sales, marketing and educational programs, and other arrangements and relationships with third- party payors, healthcare professionals, and other parties through which we market, sell and distribute our product candidates for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U. S. federal government and the states in which we conduct our business, along with foreign regulators (including European data protection authorities). See section entitled " Business – Government Regulation – Other Healthcare Laws and Compliance Requirements. " Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, collaborators, CROs or CMOs, principal investigators, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the regulations of the FDA and other comparable foreign regulatory bodies, provide true, complete and accurate information to the FDA and other comparable foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing,

discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Misconduct by persons acting on our behalf could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We and our collaborators and third- party providers are subject to national, supranational, federal or state laws and regulations, regulatory guidance and industry standards relating to data protection, privacy and information security. With respect to Europe, the collection and processing of personal data regarding (i) individuals in the EEA and ~~UK~~ **U. K.** , and / or (ii) carried out in the context of the activities of our establishments in the EEA or ~~UK~~ **U. K.** , is subject to the GDPR, as well as other national data protection legislation in force in relevant EEA member states and the ~~UK~~ **U. K.** , (including the ~~UK~~ **U. K.** Data Protection Act 2018). The GDPR is wide- ranging in scope and impose numerous obligations on companies that process personal data, including imposing special requirements in respect of the processing of **special categories of personal data (such as** health ~~and other sensitive~~ data **)** , requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring additional disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, creating mandatory data breach notification requirements in certain circumstances, requiring data protection impact assessments for high risk processing and requiring that certain measures (including contractual requirements) are put in place when engaging third- party processors. The GDPR also provides individuals with various rights in respect of their personal data, including rights of access, erasure, portability, rectification, restriction and objection. The GDPR defines personal data to include pseudonymized or coded data and require different informed consent practices and more detailed notices for clinical trial participants and investigators than applies to clinical trials conducted in the United States. We are required to apply GDPR standards to any clinical trials that our EEA and ~~UK~~ **U. K.** established businesses carry out anywhere in the world. The GDPR ~~impose~~ **imposes** strict rules on the transfer of personal data to countries outside the EEA and ~~UK~~ **U. K.** , including the United States in certain circumstances, unless a derogation exists or we incorporate a GDPR transfer mechanism (such as the European Commission approved standard contractual clauses (" SCCs ") or the ~~UK~~ **U. K.** International Data Transfer Addendum (" IDTA ")) into our agreements with third parties to govern such transfers of personal data and carry out transfer impact assessments to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal information under the GDPR, including an analysis of the laws in the recipient' s country. Carrying out such restricted transfers, therefore, comes with a significant compliance burden, requiring significant effort and expense to overcome. Failure to implement valid mechanisms for personal data transfers from Europe may result in increased exposure to regulatory actions, substantial fines, and injunctions against processing personal data from Europe. If we are unable to export personal data, this may also restrict our activities outside of Europe and require us to increase processing capabilities within Europe at significant expense or otherwise segregate our systems and operations. Switzerland has adopted similar transfer restrictions as under the GDPR. Although the ~~UK~~ **U. K.** is regarded as a third country under the EU GDPR, the European Commission issued a decision recognizing the ~~UK~~ **U. K.** as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the ~~UK~~ **U. K.** remain unrestricted. Personal data transfers from the ~~UK~~ **U. K.** to the EEA remain free flowing by virtue of a ~~UK~~ **U. K.** government adequacy decision. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR. While we have taken steps to comply with the GDPR, and implementing legislation in applicable EEA member states and the ~~UK~~ **U. K.** , including by seeking to establish appropriate lawful bases for the various processing activities we carry out as a controller or joint controller, reviewing our security procedures and those of our vendors and collaborators, and entering into data processing agreements with relevant vendors and collaborators, we cannot be certain that our efforts to achieve and remain in compliance have been, and / or will continue to be, fully successful. Given the breadth and depth of the applicable obligations, complying with the GDPR and similar data protection laws' requirements are rigorous and time intensive and require significant resources and a review of our technologies, systems and practices, as well as those of any third- party collaborators, service providers, contractors or consultants that process or transfer personal data. The ~~UK~~ **U. K.** ' s data protection regime is independent from but aligned to the EU' s data protection regime. However following the **U. K.' s departure from the European Union ("** Brexit **")** , there will be increasing scope for divergence in application, interpretation and enforcement of the data protection laws between these territories. For example, the ~~UK~~ **U. K.** has recently introduced a new Data ~~Protection & Digital Information~~ (~~No. 2~~ **Use and Access**) Bill ~~, or the Data Reform~~ **(" U. K.** Bill **")** into **parliament. If passed,** the **final version of** ~~UK legislative process with~~ the ~~intention for this~~ **U. K.** ~~bill~~ **Bill** ~~to reform~~ **may have** the ~~UK' s~~ **effect of further altering the similarities between the U. K. and EEA** data protection regime ~~following Brexit. if passed, the Data Reform Bill could reshape the UK' s data protection regime, distancing it from the EU' s data protection regime~~ and threaten the ~~UK~~ **U. K.** ' s adequacy decision from the EC. This lack of clarity on future ~~UK~~ **U. K.** laws and regulations and their interaction with those of the EU could add legal risk, uncertainty, complexity, and cost to our handling of European personal

data and our privacy and security compliance programs; and any resulting divergence in laws could increase our risk profile and may require us to implement different compliance measures for the ~~UK~~ **U. K.** and EEA. In the ~~United States~~ **U. S.**, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e. g., Section 5 of the ~~FTCA~~ **FTC Act**), that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators and third- party providers. For example, ~~California recently enacted~~ the ~~CCPA which became effective on January 1, 2020. The~~ CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA **was recently amended to apply to certain sensitive personal information and created a new state agency vested with authority to implement and enforce the CCPA. The CCPA** provides for civil penalties for violations, as well as a private right of action for data breaches that ~~is expected~~ **may lead** to ~~increase~~ **increased** ~~data breach~~ litigation. ~~US~~ **U. S.** states are constantly amending existing laws, requiring attention to frequently changing regulatory requirements ~~. At this time~~, **which may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply with them. We are conducting a clinical trial in California and therefore through our contract research organisation (CRO),** we ~~do not~~ collect personal data on residents of California ~~but should we begin to do so~~, **therefore we are** ~~and in the context of doing so, become~~ subject to the CCPA, **and** the CCPA ~~will impose~~ **imposes** ~~new and burdensome~~ privacy compliance obligations on our business and will raise new risks for potential fines and class actions. **Numerous** ~~In addition to the~~ **other U** ~~CCPA, a California ballot initiative, the CPRA, was passed in November 2020~~. **S** ~~Effective as of January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information~~. ~~The CPRA also created a new state agency vested with authority to implement and enforce the CCPA and the CPRA. The effects of the CCPA and the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and / or litigation. Some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. For example, on January 1, 2023, the CDPA became effective. Further, many additional United States~~ state privacy laws **have been enacted that** ~~will go into effect throughout 2023: the CPA (July 1, 2023); the CTDPA (July 1, 2023); and the UCPA (December 31, 2023). The CDPA, CPA, CTDPA, and UCPA~~ are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data and information governed by HIPAA. Any of these laws may broaden their scope in the future, and similar laws have been proposed on both a federal level and in more than half of the states in the United States. While **such state laws** ~~the CDPA, CPA, CTDPA, and UCPA~~ incorporate many similar concepts of the CCPA ~~and CPRA~~, there are also several key differences in the scope, application, and enforcement of the laws that will change the operational practices of regulated businesses. The new laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests ~~. A number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance~~. In addition to general privacy and data protection requirements, many jurisdictions around the world have adopted legislation that regulates how businesses operate online and enforces information security, including measures relating to privacy, **cybersecurity,** data security and data breaches. Many of these laws require businesses to notify **cybersecurity incidents and** data breaches to ~~the~~ **applicable** regulators and / or data subjects. These laws are not consistent, and compliance in the event of a widespread data breach is costly and burdensome. In many jurisdictions, enforcement actions and consequences for non- compliance with protection, privacy and information security laws and regulations are rising. In the EU and the ~~UK~~ **U. K.**, data protection authorities may impose large penalties for violations of the data protection laws, including potential fines of up to € 20 million (£ 17. 5 million in the ~~UK~~ **U. K.**) or 4 % of annual global revenue, whichever is greater. The authorities have shown a willingness to impose significant fines and issue orders preventing the processing of personal data on non- compliant businesses. Data subjects also have a private right of action, as do consumer associations, to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of applicable data protection laws. In the United States, possible consequences for non- compliance include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies ~~. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self- regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs~~. The risk of our being found in violation of these laws is increased by the fact that the interpretation and enforcement of them is not entirely clear. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare

company may run afoul of one or more of the requirements. Compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. It could also require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Failure by us or our collaborators and third- party providers to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties and orders preventing us from processing personal data), private litigation and result in significant fines and penalties against us. Moreover, clinical trial participants about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects **. The U. S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business. In 2017, the U. S. Congress and the Trump administration made substantial changes to U. S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U. S. trade, healthcare, immigration and government regulatory policy. With the transition to the Biden administration in early 2021, changes to U. S. policy occurred and since the start of the Trump Administration in 2025, U. S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U. S. policy implemented by the U. S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U. S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U. S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them** . Risks Related to Our Intellectual Property If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by in- licensing intellectual property relating to our platform technology and filing patent applications relating to our technologies that are important to our business. If we or our licensors are unable to obtain or maintain patent protection with respect to our product candidates, our competitive position, business, financial conditions, results of operations, and prospects could be materially harmed. We do not own any issued patents with respect to our product candidates and rely primarily on in- licensed patents and patent applications. We can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. Failure to obtain issued patents could have a material adverse effect on our ability to develop and commercialize our product candidates. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. In addition, it is uncertain whether the World Trade Organization (" WTO") will waive certain intellectual property protections now or in the future on certain technologies. It is unknown if such a waiver would be limited to patents, or would include other forms of intellectual property including trade secrets and confidential know- how. We cannot be certain that any of our current or future product candidates or technologies would not be subject to an intellectual property waiver by the WTO. We also cannot be certain that any of our current or future intellectual property rights, whether patents, trade secrets, or confidential know- how would be eliminated, narrowed, or weakened by such a waiver. Given the uncertain future actions by the WTO and other countries and jurisdictions around the world, including the United States, it is unpredictable how our current or future intellectual property rights or how our current or future business would be impacted. With respect to both our in- licensed and owned intellectual property, we cannot predict whether the patent applications that we and our licensors are currently pursuing or that we may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. The patent prosecution process is expensive, time- consuming, and complex, and we and our licensors may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. The patent position of biotechnology and pharmaceutical 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 may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may become subject to a third party pre- issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, post- grant and inter partes review, or interference proceedings and other similar proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products 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, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and 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, 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. Our rights to develop and commercialize our technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others and if we fail to comply with our current or future obligations in any agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We are heavily reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our product candidates. These and other future agreements impose, and may continue to impose, numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution and enforcement obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our current and future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements. In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. For example, we do not control the preparation, filing, prosecution or maintenance of patents in- licensed from OUI. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. Any termination of these licenses, or any failure of the underlying patents to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our product candidates, and competitors or other third parties would have the freedom to seek marketing authorization for, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Disputes may arise between us and our current and future licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that are not subject to the licensing agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships and the amount of fees payable as a result of sublicensing arrangements; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; • the priority of invention of any patented technology; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our current or future licensors and / or us and / or our partners. In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise 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 the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable, processes for which patents are difficult to enforce and other elements of our product discovery and development processes. Although we require all of our employees, consultants, advisors and any third

parties who have access to our proprietary know- how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary information. Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors and other third parties may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be materially and adversely harmed. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and prospects. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful and could have a material adverse effect on our business, financial conditions, results of operations and prospects. The intellectual property landscape around immunotherapeutic, nanoparticle and viral vector- based products is crowded and dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights and such claims may be costly and time- consuming and may prevent or delay our product discovery and development efforts. The intellectual property landscape around immunotherapeutic, nanoparticle and viral vector- based products is crowded and dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, inter partes review, and post- grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our licensors or strategic partners may be party to, exposed to, or threatened with, adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and / or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of viral vectors and vaccines or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. For example, we are aware of third- party patents in the United States and Europe with claims which may be relevant to our VTP- 300 and VTP- 850 product candidates. In the event that these patents were asserted against us in an infringement action, we may have to argue that the manufacture, use, sale or importation of our VTP- 300 or VTP- 850 product candidates in the United States and Europe do not infringe any valid claim of the asserted patents. There is no assurance that a court would find in our favor on questions of infringement or validity. If a third party (including any third party that controls the above referenced patents) claims that we infringe, misappropriate or otherwise violate its intellectual property rights (including the above referenced patents), we may face a number of risks, including, but not limited to: • infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time- consuming to litigate and may divert our management' s attention from our core business and may impact our reputation; • substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; • a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do, on commercially reasonable terms, or at all; • if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and / or grant cross- licenses to intellectual property rights for our products, or the license to us may be non- exclusive, which would permit third parties to use the same intellectual property to compete with us; • redesigning our product candidates or processes so they do not infringe, misappropriate or violate third party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and • 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 our share price. Some of our competitors may be able to sustain the costs of complex patent

litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects. We may choose to challenge the patentability of claims in a third party' s U. S. patent by requesting that the USPTO review the patent claims in an ex- parte reexamination, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party' s patent in patent opposition proceedings in the European Patent Office (" EPO") or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies. Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is " clear and convincing, " a heightened standard of proof. There may be issued third- party patents of which we are currently unaware with claims to compositions of matter, methods of manufacture or methods for treatment related to our product candidates, their manufacture or use. Patent applications can take many years to issue. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in- license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms, or at all, or may only be available on a non- exclusive basis. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our product candidates, process for their manufacture or methods of use, including combination therapies or participant selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patent applications or any patents we in-license or may own in the future is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in- licenses. We currently have rights to intellectual property, through licenses from third parties, to develop and commercialize our product candidates. Many pharmaceutical companies, biotechnology companies, and academic institutions are competing with us in the ~~field~~ **fields** of infectious disease, ~~immune tolerance~~ **I & I** and oncology and filing patent applications potentially relevant to our business. Because our current and future product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in- license or use these proprietary rights. Our product candidates may also require particular vector components or gene sequences encoding antigenic peptides to work effectively and efficiently and these rights may be held by others. Similarly, efficient production, delivery or use of our product candidates may also require specific compositions

or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that will be used with our product candidates may be covered by the intellectual property rights of others. Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program and allowing third parties to compete with us. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such ~~program~~ **programs** and our business and financial condition could suffer. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. 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 enable us to make an appropriate return on our investment or at all. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business, results of operations, financial condition and prospects could suffer. We may be involved in lawsuits to protect or enforce our intellectual property rights, including any patents we may own or in- license in the future, which could be expensive, time- consuming and unsuccessful. Competitors may infringe any patents we in- license or may own in the future. In addition, any patents we may in-license or own also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may in- license or own in the future is not valid or is unenforceable or that the other party' s use of our technology falls under the safe harbor to patent infringement under 35 U. S. C. § 271 (e) (1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question or that such third party' s activities do not infringe our patents. An adverse result in any litigation or defense proceedings could put one or more of any patents we in- license or may own in the future at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. 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 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 and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Post- grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may in- license or own in the future. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices, where our foreign patents are challenged. For example, one of our in- licensed European patents relating to our now discontinued MVA influenza product candidate has been revoked in a European opposition proceeding. This decision is currently on appeal, although there can be no assurance that any such appeal will be successful. The costs of opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs

and distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. We may not be able to detect infringement of any patents we may in- license or own. Even if we detect infringement by a third party of any such patents, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in- license against such third party. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition. Any issued patents we in- license or may own now or in the future covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO. If we or our licensors or strategic partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, inter partes review, post- grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our in- licensed patent applications or patents or any patent applications or patents we may own in the future in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we in-license or may own in the future, allow third parties to commercialize our product candidates or other technologies 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. 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. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non- exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects. We may be subject to claims challenging the inventorship or ownership of any intellectual property, including any patents we may in- license or own in the future. We may be subject to claims that former employees, collaborators or other third parties have an interest in any patents we in- license or may own in the future, trade secrets, or other intellectual property as an inventor or co- inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time- consuming. Litigation may be necessary to defend

against these and other claims challenging inventorship of any patents we in- license or may own in the future, trade secrets or other intellectual property. If we were unsuccessful, in addition to paying monetary damages, we could lose valuable rights in intellectual property that we regard as our own, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non- competition or non- solicitation agreements with our competitors or other third parties. We have received confidential and proprietary information from third parties. In addition, as is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information or trade secrets of these third parties. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims and possible aftermath could result in substantial cost and be a distraction to our management and employees. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition. In addition, 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 our share price. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements that provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property, we may be unsuccessful in executing such an agreement with each party who, in fact, develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates we may develop, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates we may develop, one or more U. S. patents we in- license or may own in the future may be eligible for limited patent term extension under the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, 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 the term of any such extension is shorter than what we request, our competitors or other third parties may obtain approval of competing products following expiration of any patents that issue from our patent applications, and our business, financial condition, results of operations, and prospects could be materially harmed. Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. For example, in the case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U. S. Supreme Court held that certain claims to DNA molecules are not patentable. Any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce any rights we may have in our patent applications or any patents we may own or in- license in the future. Recent or future patent

reform legislation could also increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents we in- license or may own in the future. The United States has enacted and implemented wide- ranging patent reform legislation. On September 16, 2011, the Leahy- Smith America Invents Act (" America Invents Act"), was signed into law, which includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, establish a new post- grant review system and switch the U. S. patent system from a " first- to- invent " system to a " first- to- file " system. Under a " first- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or other technologies or (ii) invent any of the inventions claimed in our patent applications or any patents we may own or in- license. These changes also allow third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. 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. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products 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. Accordingly, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents we in- license or may own in the future, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our European patents and patent applications could be challenged in the recently created Unified Patent Court (UPC) for the European Union, that **was** ~~is expected to be~~ fully ratified **and came into being** in 2023. We may decide to opt out our European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Under the UPC, a granted European patent would be valid and enforceable in numerous European countries. A successful invalidity challenge to a European patent under the UPC would result in loss of patent protection in those European countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European countries, rather than in each validated European country separately as such patents always have been adjudicated. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. We may not be able to protect our intellectual property and proprietary rights throughout the world. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, our intellectual property license agreements may not always include worldwide rights. 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 or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. As a result, in response to the COVID- 19 pandemic, it is possible that certain countries may take steps to facilitate compulsory licenses that permit the distribution of a COVID- 19 vaccine in those countries. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the relevant patent rights. If we or any of our licensors is 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, financial condition, results of operations, and prospects may be adversely affected. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business

may be adversely affected. Our trademarks or trade names may be challenged, infringed or diluted, lapsed, abandoned, circumvented or declared generic or determined to be infringing on or become dilutive of other marks, or otherwise invalidated through administrative process or litigation. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. Third parties may use trademarks similar to our trademarks and any potential confusion as to the source of goods or services could have an adverse effect on our business. For example, in April 2022, we received a letter asserting that our use of our " Vaccitech " trademark infringes a United Kingdom trademark held by a third party. We timely responded rejecting the claims and we believe that such claims are without merit. However, if such third party continues to assert its claims, we cannot provide any assurance whether we could reach a settlement relating to such claims or whether we would prevail in any litigation or action related to such claims. Moreover, during the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademarks. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, at the USPTO and at comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and / or to seek the cancellation of registered trademarks through opposition or cancellation proceedings against our trademarks, and if such third parties are successful, our trademarks may not survive such proceedings. In some cases, there may be third- party trademark owners who have prior rights to our trademarks or third parties who have prior rights to similar trademarks, and we may not be able to prevent such third parties from using and marketing any such trademarks. Litigation brought to protect and enforce our intellectual property rights could be costly, unpredictable, time- consuming and distracting to management, regardless of whether we are successful in such litigation. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business, results of operations and financial condition may be adversely affected. Numerous factors may limit any potential competitive advantage provided by the relevant patent rights. The degree of future protection afforded by our intellectual property rights, whether owned or in- licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative: • patent applications that we own or in- license may not lead to issued patents; • patents, that we in- license or may own in the future, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable; • others may be able to develop and / or practice technology, including compounds that are similar to the chemical compositions of our product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we in- license or may own in the future; • third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection; • we, or our licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or in- license; • we, or our licensors or collaborators, might not have been the first to file patent applications covering a particular invention; • others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights; • our competitors or other third parties might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not be able to obtain and / or maintain necessary licenses on reasonable terms, or at all; • third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property; • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such trade secrets or know- how; • we may not be able to maintain the confidentiality of our trade secrets or other proprietary information; • we may not develop or in- license additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects. Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Employee Matters **The pipeline prioritization and restructuring may be unsuccessful, lead to additional costs, disrupt our operations, create unintended problems in our workforce, or increase litigation risk, in which case our business could be harmed. On June 12, 2024, we announced plans to prioritize our pipeline to focus on the development of VTP- 300 in CHB and VTP- 1000 in celiac disease, including a workforce reduction of approximately 25 %. On January 10, 2025, we announced a restructuring plan that aims to prioritize our immune tolerance research and development programs, including a 65 % reduction in workforce. We are planning to partner the further development of VTP- 300 and plan to report the primary analysis data from HBV003 in the second quarter of 2025. Despite our efforts, the pipeline prioritization and restructuring may be unsuccessful, lead to additional costs, disrupt our operations, create unintended problems in our workforce, and increase litigation risk, which could harm our business and results of operations. We may incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the pipeline prioritization and restructuring. We may not realize, in full or in part, the anticipated benefits and savings from the pipeline prioritization and restructuring due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the pipeline prioritization and restructuring, our operating results and financial condition would be adversely affected. Moreover, our decision to focus on the development of VTP- 300 in CHB and VTP- 1000 in celiac disease may cause us to fail to capitalize on viable commercial products or profitable market opportunities or limit the opportunities we are able to pursue. In addition, we may need to undertake**

additional workforce reductions or restructuring activities in the future. Furthermore, the pipeline prioritization and restructuring could yield unanticipated consequences, such as increased difficulties in our day- to- day operations, the loss of institutional knowledge and expertise, attrition beyond planned workforce reductions, reduced employee morale, and difficulty attracting and retaining qualified management, scientific, and other personnel critical to our business. In addition, while positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. If employees who were not affected by the workforce reduction pursue alternative employment, we may need to seek contractor support, which could harm our productivity and add unplanned expense. The implementation of the workforce restructuring could also lead to litigation brought by or on behalf of our former employees. We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including Bill Enright, our Chief Executive Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business **. As previously announced on January 10, 2025, Graham Griffiths will step down from his role as Chief Operating Officer on June 30, 2025, and Gemma Brown will step down from her role as Chief Financial Officer on April 30, 2025. The departure of key leadership personnel can result in loss of significant knowledge and experience from the company. This loss of knowledge and experience can be mitigated through successful hiring and transition, but there can be no assurance that we will be successful in such efforts. Attracting and retaining qualified senior leadership may be more challenging under adverse business conditions. Failure to attract and retain the right talent, or to smoothly manage the transition of responsibilities resulting from such turnover, would affect our ability to meet our challenges and may cause us to miss performance objectives or financial targets** . We conduct our operations at our facilities in Harwell, United Kingdom and Germantown, Maryland. These regions are headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in these markets is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. Changes to U. K., U. S. or similar foreign immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to the U. K. (including, but not limited to, those that result as a direct or indirect consequence of Brexit), U. S. or similar foreign immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U. S. citizens. To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on ~~short~~ notice **periods specified in their employment agreements** . Although we have employment agreements with all our employees, these employment agreements with U. S. employees provide for at- will employment, which means that any of our U. S. employees could leave our employment at any time, by providing the required contractual notification of their intent to leave. The standard notice period for U. K. employed personnel is three calendar months or six calendar months for the senior executive team. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid- level and senior scientific and medical personnel. Risks Related to Our Business Operations and Growth We will need to grow the size of our organization, and we may experience difficulties in managing this growth. As of December 31, ~~2023~~ **2024** , we had ~~130~~ **105** full- time and part- time employees. ~~As~~ **In connection with the restructuring announced in January 2025, we are planning a 65 % reduction in force, but as** our development and commercialization plans and strategies develop ~~, and as we continue to transition into operating as a public company~~ , we expect to need additional managerial, operational, technical, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining and motivating additional and existing employees; • managing clinical trial sites in multiple countries; • managing our internal development efforts effectively, including the clinical and regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing authorization for our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research,

development and commercialization goals. Our internal computer systems, or those used by our third- party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in the disclosure of confidential or proprietary information, including personal data, damage to our reputation, and subject us to significant financial and legal exposure and cause a material disruption of the development programs of our product candidates. We and our third- party CROs and other contractors and consultants rely extensively on information technology systems to conduct and manage our business. Despite the implementation of security measures, our internal computer systems and those of our current and future third- party providers are vulnerable to damage from computer viruses and unauthorized access **, including cybersecurity incidents and data breaches** . The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Cyberattacks could include wrongful conduct by **insider employees or vendors,** hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, **including ransomware,** denial- of- service, social engineering fraud **, including phishing attacks, data breaches,** or other means to threaten data security, confidentiality, integrity and availability. If such an event were to occur, it could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and result in a material disruption of our development programs and our business operations, such as the loss of clinical trial data from completed or future clinical trials. Such loss could result in delays in our marketing authorization efforts and significantly increase our costs to recover or reproduce the data. Although we devote resources to protect our information systems, including organization- wide prevention software, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches **or data breaches** that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our business, financial condition, results of operations and prospects. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches **. Like other companies in our industry, we, and our third party vendors, have experienced and will continue to experience threats and cybersecurity incidents relating to our information technology systems and infrastructure** . Any breach in our or our third- party providers' information technology systems could lead to the unauthorized access, disclosure and use of non- public information, including information from our participant registry or other participant information, which is protected by HIPAA, and other laws. Any such access, disclosure, or other loss of information could result in legal **notifications and disclosures, legal** claims or proceedings, liability under laws that protect the privacy of personal information, damage to our reputation and the further development and commercialization of our product candidates could be delayed. If we or our third- party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third- party providers could have difficulty preventing, detecting and controlling such cyberattacks and any such attacks could result in losses described above as well as disputes with physicians, participants and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. If we are unable to prevent or mitigate the impact of such ~~security~~ **cybersecurity** or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business **. Further, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach** . Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, pandemics and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third- party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any product candidate for which we receive marketing authorization. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our product candidates or products that we may develop; • injury to our reputation; • withdrawal of clinical trial participants; • initiation of investigations by regulators; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or participants; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; • the

inability to commercialize any product candidate; and • a decline in our share price. Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. In the future, we may be unable to maintain this insurance coverage, or we may not be able to obtain additional or replacement coverage at a reasonable cost, if at all. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. ~~The most recent~~ **In the past,** global financial ~~crisis~~ **crises have** caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our third- party suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Risks Related to Our International Operations A variety of risks associated with operating our business internationally could materially adversely affect our business. We plan to seek marketing authorization for our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including: • differing regulatory requirements in foreign countries; • unexpected changes in tariffs **(including tariffs that have been or may in the future be imposed by the United States or other countries), trade protection measures** , trade barriers **(including further legislation or actions taken by the United States or other countries that restrict trade)** , price and exchange controls, and other regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • potential liability under the FCPA Office of Foreign Assets Control Anti- Money Laundering Program as required by the Bank Secrecy Act and its implementing regulations, or comparable foreign laws, including the ~~UK~~ **U. K.** Bribery Act 2010 (" Bribery Act"); • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from ~~geo-political~~ **geopolitical** actions, including war and terrorism. These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations. Our business is subject to economic, political, regulatory and other risks associated with international operations. Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including the following: • economic weakness, including inflation, political instability in particular in foreign economies and markets; • differing regulatory requirements for drug approvals; • differing jurisdictions potentially presenting different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions; • potentially reduced protection for intellectual property rights; • difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations; • changes in regulations and customs, tariffs and trade barriers; • changes in currency exchange rates of the euro, U. S. dollar, pound sterling and currency controls; • changes in a specific country' s or region' s political or economic environment; • trade protection measures, import or export licensing requirements or other restrictive actions by governments; • differing reimbursement regimes and price controls in certain international markets; • negative consequences from changes in tax laws or practice; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • workforce uncertainty in countries where labor unrest is more common than in the United States and EU; • difficulties associated with staffing and managing international operations, including differing labor relations; • business interruptions resulting from ~~geo- political~~ **geopolitical** actions, including war, terrorism, pandemics, or natural disasters including earthquakes, typhoons, floods and fires. Claims of U. S. civil liabilities may not be enforceable against us. We are incorporated under English law and have our registered office in England. Many of the members of our senior management and certain members of our board of directors are non- residents of the United States, and all or a substantial portion of our assets and the assets of such persons are held outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U. S. courts against them or us based on civil liability provisions of the U. S. federal securities laws. The United States and the ~~UK~~ **U. K.** do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U. S. securities laws, would not automatically be recognized or enforceable in the ~~UK~~ **U. K** . In addition, uncertainty exists as to whether the courts of England and Wales would entertain original actions brought in the ~~UK~~ **U. K.** against us or our directors or senior management predicated upon securities laws of the U. S. or any state in the United States. Any final and conclusive monetary judgment for a definite sum obtained against us in U. S. courts would be treated by the courts of England and Wales as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain requirements are met. Whether these requirements are met in respect of a judgment

based upon the civil liability provisions of the U. S. securities laws, including whether the award of monetary damages under such laws would constitute a penalty, is an issue for the court making such decision. If the courts of England and Wales give a judgment for the sum payable under a U. S. judgment, the English judgment will be enforceable by methods generally available for this purpose. These methods generally permit the courts of England and Wales discretion to prescribe the manner of enforcement. As a result, U. S. investors may not be able to enforce against us or certain of our senior management, board of directors or certain experts named herein who are residents of the ~~UK~~ **U. K.** or countries other than the United States any judgments obtained in U. S. courts in civil and commercial matters, including judgments under the U. S. federal securities laws. Fluctuations in the exchange rate between the U. S. dollar and the pound sterling may increase the risk of holding our ADSs and may materially affect our results of operations and financial condition. Our ADSs trade on Nasdaq in U. S. dollars. Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly the U. S. dollar, the pound sterling and the euro. Our reporting currency is denominated in U. S. dollars and our functional currency is the pound sterling (except that the functional currency of our U. S. subsidiaries is the U. S. dollar) and the majority of our operating expenses are paid in pound sterling. We also regularly acquire services, consumables and materials in U. S. dollars, ~~pound~~ **pounds** sterling, AUS dollars and the euro. Further potential future revenue may be derived ~~from abroad,~~ particularly from the United States. As a result, our business and the price of our ADSs may be affected by fluctuations in foreign exchange rates between the pound sterling and these other currencies, which may also have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place. See Note 3 in the notes to our annual financial statements appearing elsewhere in this Annual Report for a description of foreign exchange risks. ~~The possible abandonment of the euro by one or more members of the European Union could materially affect our business in the future. Despite measures taken by the EU to provide funding to certain EU member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re- introduction of individual currencies in one or more EU member states, or in more extreme circumstances, the dissolution of the EU. The effects on our business of a potential dissolution of the EU, the exit of one or more EU member states from the EU or the abandonment of the euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.~~ In addition, as a result of fluctuations in the exchange rate between the U. S. dollar and the pound sterling, the U. S. dollar equivalent of the proceeds that a holder of ADSs would receive upon the sale in the U. K. of any ordinary shares withdrawn from the depositary and the U. S. dollar equivalent of any cash dividends paid in euros on our ordinary shares represented by ADSs could also decline. Risks Related to Ownership of Our ADSs An active trading market for our ADSs may not be sustained. Prior to our IPO in May 2021, there had been no public trading market for our ADSs. Although our ADSs are listed on ~~The~~ **the** Nasdaq Global Market, an active trading market for our shares may not be sustained. If an active market for our ADSs is not sustained, it may be difficult for holders of our ADSs to sell ADSs without depressing the market price for the shares, or at all. Further, an inactive market may also impair our ability to raise capital by selling our ADSs and may impair our ability to enter into strategic partnerships or acquire companies or products by using our ADSs as consideration. Our principal shareholders and management own a significant percentage of our stock and exert significant influence over matters subject to shareholder approval. As of March 14, ~~2024~~ **2025** , our executive officers, directors, and 5 % shareholders beneficially owned approximately ~~42~~ **52** % of our voting stock. Depending on the level of attendance at our meetings of shareholders, these shareholders either alone or voting together as a group may be in a position to determine or significantly influence the outcome of decisions taken at any such meeting. Any shareholder or group of shareholders controlling more than 50 % of the share capital present and voting at our meetings of shareholders may control any shareholder resolution requiring a simple majority, including the appointment of board members, certain decisions relating to our capital structure and the approval of certain significant corporate transactions. This may prevent or discourage unsolicited acquisition proposals or offers for our ADSs that holders of our ADSs may feel are in their best interest as shareholders. The price of our ADSs is volatile and holders of our ADSs could lose all or part of their investment. The trading price of our ADSs is highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report, these factors include: • the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates; • adverse results or delays in preclinical studies and clinical trials; • our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial; • any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive marketing authorization for our product candidates; • changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals; • adverse developments concerning our manufacturers or our manufacturing plans; • our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices; • our inability to establish collaborations if needed; • our failure to commercialize our product candidates; • additions or departures of key scientific or management personnel; • unanticipated serious safety concerns related to the use of our product candidates; • introduction of new products or services offered by us or our competitors; • announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; • our ability to effectively manage our growth; • the size and growth of our initial cancer target markets; • our ability to successfully treat additional types of cancers or at different stages; • actual or anticipated variations in quarterly operating results; • our cash position; • our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; • publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts; • changes in the market valuations of similar companies; • overall performance of the equity markets; • sales of our ADSs by us or our shareholders in the future; • trading

volume of our ADSs; • changes in accounting practices; • ineffectiveness of our internal controls; • disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including intellectual property or shareholder litigation; • general political and economic conditions; and • other events or factors, many of which are beyond our control. In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ADSs, regardless of our actual operating performance. Holders of our ADSs are not treated as holders of our ordinary shares. Holders of ADSs are not treated as holders of our ordinary shares, unless they withdraw the ordinary shares underlying their ADSs in accordance with the deposit agreement and applicable laws and regulations. The depositary is the holder of the ordinary shares underlying our ADSs. Holders of ADSs therefore do not have any rights as holders of our ordinary shares, other than the rights that they have pursuant to the deposit agreement. Holders of our ADSs will not have the same voting rights as the holders of our ordinary shares, and may not receive voting materials or any other documents that would need to be provided to our shareholders pursuant to English corporate law, including the Companies Act 2006, in time to be able to exercise their right to vote. Except as described elsewhere in this Annual Report and the deposit agreement, holders of the ADSs will not be able to exercise voting rights attaching to the ordinary shares represented by the ADSs. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon our request, the depositary shall distribute to the holders as of the record date (i) the notice of the meeting or solicitation of consent or proxy sent by us and (ii) a statement as to the manner in which instructions may be given by the holders. We cannot guarantee that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADSs. Otherwise, ADS holders will not be able to exercise their right to vote, unless they withdraw the ordinary shares underlying the ADSs they hold to vote them in person or by proxy in accordance with applicable laws and regulations and our articles of association. However, ADS holders may not know about the meeting far enough in advance to withdraw those ordinary shares. A shareholder is only entitled to participate in, and vote at, the meeting of shareholders, provided that it holds our ordinary shares as of the record date set for such meeting and otherwise complies with our Articles. In addition, the depositary' s liability to ADS holders for failing to execute voting instructions or for the manner of executing voting instructions is limited by the deposit agreement. As a result, ADS holders may not be able to exercise their right to vote, and there may be nothing they can do if the ordinary shares underlying their ADSs are not voted as they requested or if their shares cannot be voted. Holders of ADSs may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying ordinary shares. ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason, subject to the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders meeting or we are paying a dividend on our ordinary shares. In addition, ADS holders may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities. ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff (s) in any such action. The deposit agreement governing our ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, holders and beneficial owners of ADSs irrevocably waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ADSs or the deposit agreement. If this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre- dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre- dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non- exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre- dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and our ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement. If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or our ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and / or the depositary. If a lawsuit is brought against us and / or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff (s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing. No condition, stipulation or provision of

the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with U. S. federal securities laws and the rules and regulations promulgated thereunder. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. Although we have obtained research coverage from certain analysts, there can be no assurance that analysts will continue to cover us, or provide favorable coverage. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our ADSs less attractive to investors. We are an emerging growth company, as defined in the JOBS Act enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we became a public company, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date we became a public company, (b) in which we have total annual gross revenue of at least $ 1. ~~24~~ **235** billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our ADSs that are held by non- affiliates to exceed $ 700 million as of the prior June 30th, and (2) the date on which we have issued more than $ 1 billion in non- convertible debt during the prior three- year period. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same timing of adoption of 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 company, " which may allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements. We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our stock price may be more volatile. We will incur increased costs as a result of operating as an English public company listed in the U. S., and our board of directors will be required to devote substantial time to new compliance initiatives and corporate governance practices. As an English public company listed in the U. S., ~~and particularly after~~ we ~~no longer qualify as an emerging growth company, we will~~ incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on foreign reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors, management and other personnel ~~will~~ need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations ~~will~~ increase our legal and financial compliance costs and ~~will~~ make some activities more time- consuming and costly. For example, ~~we expect that~~ these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors **. In addition, after we no longer qualify as an emerging growth company, we expect to incur additional legal, accounting and other expenses** . However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes- Oxley Act and the rules and regulations of The Nasdaq Global Market. Pursuant to Section 404 of the Sarbanes- Oxley Act, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal control over financial reporting. See section entitled " Controls and Procedures – Management' s Annual Report on Internal Controls Over Financial Reporting. " However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We will incur substantial additional professional fees and internal costs to expand our accounting and finance functions and expend significant management efforts. General Risk Factors Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance. Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and / or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and, if approved, sales of our product candidates. These upfront and milestone payments may vary significantly from period to

period and any variance could cause a significant fluctuation in our operating results from one period to the next. Further, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following: • the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time; • the timing and outcomes of clinical trials for our current and any other future product candidates; • the cost of manufacturing our current and any future product candidates, which may vary depending on regulatory guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers; • our ability to adequately support our future growth; • potential unforeseen business disruptions that increase our costs or expenses; • future accounting pronouncements or changes in our accounting policies; and • the changing and volatile global economic environment. The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our ADSs could decline substantially. The price of our ADSs could decline even when we have met any previously publicly stated revenue and / or earnings guidance we may provide. Holders of our ADSs may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs. The depositary for the ADSs has agreed to pay to holders of our ADSs the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. Shareholders will receive these distributions in proportion to the number of our ordinary shares ~~our~~ **those** ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit distribution on the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that holders of our ADSs may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to holders of our ADSs. These restrictions may have an adverse effect on the value of our ADSs. We do not intend to pay dividends on our ADSs, so any returns will be limited to the value of our ordinary shares. Under current English law, a company' s accumulated realized profits must exceed its accumulated realized losses (on a non- consolidated basis) before dividends can be declared and paid. Therefore, we must have distributable profits before declaring and paying a dividend. In addition, as a public limited company incorporated in England ~~&~~ **and** Wales, we will only be able to make a distribution if the amount of our net assets is not less than the aggregate of our called- up share capital and undistributable reserves and if, and to the extent that, the distribution does not reduce the amount of those assets to less than that aggregate. We have not paid dividends in the past on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our ADSs. Any return to shareholders and holders of our ADSs will therefore be limited to the appreciation of their stock, which may never occur. As an English public limited company, certain capital structure decisions require shareholder approval, which limits our flexibility to manage our capital structure. English law provides that a board of directors may only allot shares (or grant rights to subscribe for or to convert any security into shares) with the prior authorization of shareholders, such authorization stating the aggregate nominal amount of shares that it covers and being valid for a maximum period of five years, each as specified in our Articles or relevant ordinary resolution passed by shareholders at a general meeting. Such authority from our shareholders to allot shares (or grant rights to subscribe for or to convert any security into shares) for a period of five years from April 21, 2021 was included in the ordinary resolution passed by our shareholders on April 21, 2021, which authorization will need to be renewed upon expiration (i. e., at least every five years) but may be sought more frequently for additional five- year terms (or any shorter period). English law also generally provides shareholders with preemptive rights when new shares are issued for cash. However, it is possible for the Articles, or for shareholders to pass a special resolution at a general meeting, being a resolution passed by at least 75 % of the votes cast, to disapply preemptive rights. Such a disapplication of preemptive rights may be for a maximum period of up to five years from the date of adoption of the Articles, if the disapplication is contained in the Articles, but not longer than the duration of the authority to allot shares to which this disapplication relates or from the date of the shareholder special resolution, if the disapplication is by shareholder special resolution. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i. e., at least every five years). Such authority from our shareholders to disapply preemptive rights for a period of five years was included in the special resolution passed by our shareholders on April 21, 2021, which disapplication will need to be renewed upon expiration (i. e., at least every five years) to remain effective, but may be sought more frequently for additional five- year terms (or any shorter period). English law also generally prohibits a public company from repurchasing its own shares without the prior approval of shareholders by ordinary resolution, being a resolution passed by a simple majority of votes cast, and other formalities. Such approval may be for a maximum period of up to five years. Shareholder protections found in provisions under the ~~UK~~ **U. K.** City Code on Takeovers and Mergers (the" Takeover Code"), will not apply if our place of central management and control is considered to be outside of the ~~UK~~ **U. K.** (or the Channel Islands or the Isle of Man). We believe that our place of central management and control is not in the United Kingdom (or the Channel Islands or the Isle of Man) for the purposes of the jurisdictional criteria of the Takeover Code. Accordingly, we believe that we are not currently subject to the Takeover Code and, as a result, our shareholders are not currently entitled to the benefit of certain takeover offer protections provided under the Takeover Code, including the rules regarding mandatory takeover bids. In the event that this changes, or if the interpretation and application of the Takeover Code

by the Panel on Takeovers and Mergers, (the" Takeover Panel"), changes (including changes to the way in which the Takeover Panel assesses the application of the Takeover Code to English companies whose shares are listed outside of the United Kingdom), the Takeover Code may apply to us in the future. The Takeover Code provides a framework within which takeovers of companies which are subject to the Takeover Code are regulated and conducted. The following is a brief summary of some of the most important rules of the Takeover Code: • in connection with a potential offer, if following an approach by or on behalf of a potential bidder, the company is " the subject of rumor or speculation " or there is an " untoward movement " in the company' s share price, there is a requirement for the potential bidder to make a public announcement about a potential offer for the company, or for the company to make a public announcement about its review of a potential offer; • when any person acquires, whether by a series of transactions over a period of time or not, an interest in shares which (taken together with shares already held by that person and an interest in shares held or acquired by persons acting in concert with him or her) carry 30 % or more of the voting rights of a company that is subject to the Takeover Code, that person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights in that company to acquire the balance of their interests in the company; • when any person who, together with persons acting in concert with him or her, is interested in shares representing not less than 30 % but does not hold more than 50 % of the voting rights of a company that is subject to the Takeover Code, and such person, or any person acting in concert with him or her, acquires an additional interest in shares which increases the percentage of shares carrying voting rights in which he or she is interested, then such person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights of that company to acquire the balance of their interests in the company; • a mandatory offer triggered in the circumstances described in the two paragraphs above must be in cash (or be accompanied by a cash alternative) and at not less than the highest price paid within the preceding 12 months to acquire any interest in shares in the company by the person required to make the offer or any person acting in concert with him or her; • in relation to a voluntary offer (i. e., any offer which is not a mandatory offer), when interests in shares representing 10 % or more of the voting rights of a class have been acquired for cash by an offeror (i. e., a bidder) and any person acting in concert with it in the offer period and the previous 12 months, the offer must be in cash or include a cash alternative for all shareholders of that class at not less than the highest price paid for any interest in shares of that class by the offeror and by any person acting in concert with it in that period. Further, if an offeror acquires for cash any interest in shares during the offer period, a cash alternative must be made available at not less than the highest price paid for any interest in the shares of that class; • if, after making an offer for a company, the offeror or any person acting in concert with them acquires an interest in shares in an offeree company (i. e., a target) at a price higher than the value of the offer, the offer must be increased to not less than the highest price paid for the interest in shares so acquired; • an offeree company must appoint a competent independent adviser whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company; • special or favorable deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial adviser to the offeree; • all shareholders must be given the same information; • each document published in connection with an offer by or on behalf of the offeror or offeree must state that the directors of the offeror or the offeree, as the case may be, accept responsibility for the information contained therein; • profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisers; • misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately; • actions during the course of an offer by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans. Frustrating actions would include, for example, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group; • stringent and detailed requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1 % or more of any class of relevant securities; and • employees of both the offeror and the offeree company and the trustees of the offeree company' s pension scheme must be informed about an offer. In addition, the offeree company' s employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment appended to the offeree board of directors' circular or published on a website. The rights of our shareholders may differ from the rights typically offered to shareholders of a U. S. corporation. We are incorporated under the laws of England and Wales. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by the laws of England and Wales, including the provisions of the **U. K.** Companies Act 2006, and by our Articles. These rights differ in certain respects from the rights of shareholders in typical U. S. corporations. The principal differences include the following: • under English law and our Articles, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U. S. law, each shareholder typically is entitled to one vote per share at all meetings; • under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depositary bank; • under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U. S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise; • under English law and our Articles, certain matters require the approval of 75 % of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll of shareholders representing 75 % of the ordinary shares voting (in person or by proxy)), including amendments to the Articles. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U. S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve certain

significant transactions; • in the ~~UK~~ **U. K.** , takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares / ADSs. If acceptances are not received for 90 % or more of the ordinary shares / ADSs under the offer, under English law, the bidder cannot complete a " squeeze out " to obtain 100 % control of us. Accordingly, acceptances of 90 % of our outstanding ordinary shares (including those represented by ADSs) will likely be a condition in any takeover offer to acquire us, not 50 % as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100 % control of us, requires the approval of a majority of shareholders voting at the meeting and representing 75 % of the ordinary shares (including those represented by ADSs) voting for approval; • under English law and our Articles, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U. S. law; and • the quorum requirement for a shareholders' meeting is one or more qualifying persons present at a meeting and between them holding (or being the proxy or corporate representative of the holders of) at least thirty- three and one- third percent (33 1 / 3 %) in number of the issued shares (excluding any shares held as treasury shares) entitled to attend and vote on the business to be transacted. Under U. S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company' s certificate of incorporation or bylaws, but typically not below one- third of the shares entitled to vote at the meeting. Our Articles provide that the courts of England and Wales are the exclusive forum for the resolution of all shareholder complaints other than complaints asserting a cause of action arising under the Securities Act or the Exchange Act, and that the United States District Court for the Southern District of New York will be the exclusive forum for the resolution of any shareholder complaint asserting a cause of action arising under the Securities Act or the Exchange Act. Our Articles provide that, unless we consent by ordinary resolution to the selection of an alternative forum, the courts of England and Wales shall, to the fullest extent permitted by law, be the exclusive forum for: (a) any derivative action or proceeding brought on our behalf; (b) any action or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us; (c) any action or proceeding asserting a claim arising out of any provision of the **U. K.** Companies Act 2006 or our Articles (as may be amended from time to time); or (d) any action or proceeding asserting a claim or otherwise related to our affairs (the " England and Wales Forum Provision " ~~.~~) **.** The England and Wales Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our Articles further provide that unless we consent by ordinary resolution to the selection of an alternative forum, the United States District Court for the Southern District of New York shall be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act or the Exchange Act (the " U. S. Federal Forum Provision ~~.~~") **.** In addition, our Articles provide that any person or entity purchasing or otherwise acquiring any interest in our shares is deemed to have notice of and consented to the England and Wales Forum Provision and the U. S. Federal Forum Provision; provided, however, that our shareholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. The England and Wales Forum Provision and the U. S. Federal Forum Provision in our Articles may impose additional litigation costs on our shareholders in pursuing any such claims. Additionally, the forum selection clauses in our Articles may limit the ability of our shareholders to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our shareholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are " facially valid " under Delaware law, there is uncertainty as to whether other courts, including the courts of England and Wales and other courts within the U. S., will enforce our U. S. Federal Forum Provision. If the U. S. Federal Forum Provision is found to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our results of operations and financial condition. The U. S. Federal Forum Provision may also impose additional litigation costs on our shareholders who assert that the provision is not enforceable or invalid. The courts of England and Wales and the United States District Court for the Southern District of New York may also reach different judgments or results than would other courts, including courts where a shareholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders. Changes in U. S. tax law could adversely affect our financial condition and results of operations. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our ordinary shares or ADSs. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U. S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U. S. tax laws on an investment in our ordinary shares or ADSs. ~~If~~ **We believe** we were ~~classified as~~ a passive foreign investment company **(" PFIC")** , ~~it~~ **for prior taxable years and we may be a PFIC in future taxable years, which** ~~would~~ **could** result in adverse U. S. federal income tax consequences to U. S. Holders. Under the Internal Revenue Code (the" Code"), we will be a passive foreign investment company, or PFIC, for any taxable year in which (i) 75 % or more of our gross income consists of passive income or (ii) 50 % or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For **the** purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for

purposes of the above calculations, a non- U. S. corporation that directly or indirectly owns at least 25 % by value of the shares of another corporation is treated as holding and receiving directly its proportionate share of assets and income of such corporation. If we are a PFIC for any taxable year during which a U. S. Holder holds our ordinary shares or ADSs, the U. S. Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred and additional reporting requirements. A " U. S. Holder " is a holder who, for U. S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs and is: (i) an individual who is a citizen or individual resident of the United States; (ii) a corporation, or other entity taxable as a corporation for U. S. federal income tax purposes, created or organized in or under the laws of the United States, any state therein or the District of Columbia; (iii) an estate the income of which is subject to U. S. federal income taxation regardless of its source; or (iv) a trust if (1) a U. S. court is able to exercise primary supervision over the administration of the trust and one or more U. S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U. S. person under applicable U. S. Treasury Regulations. Based on the current and expected composition of our income and the value of our assets, we were a PFIC for the year ended December 31, ~~2023~~ **2024** and expect to remain a PFIC for our current taxable year. No assurances regarding our PFIC status can be provided for the current taxable year or any future taxable years. The determination of whether we are a PFIC is a fact- intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by the spending of the cash we raise in any offering. Each U. S. Holder should consult its own tax advisors with respect to the potential adverse U. S. tax consequences to it if we are or were to become a PFIC. If we ~~were~~ **are** a PFIC for any taxable year during which a U. S. investor owns ADSs, certain adverse U. S. federal income tax consequences could apply to such U. S. investor. We will provide the information necessary for a U. S. investor to make a qualified electing fund election with respect to us. If we are a controlled foreign corporation, there could be adverse U. S. federal income tax consequences to certain U. S. Holders. Each " Ten Percent Shareholder " (as defined below) in a non- U. S. corporation that is classified as a " controlled foreign corporation, " or a CFC, for U. S. federal income tax purposes generally is required to include in income for U. S. federal tax purposes such Ten Percent Shareholder' s pro rata share of the CFC' s " Subpart F income, " " global intangible low- taxed income " and investment of earnings in U. S. property, even if the CFC has made no distributions to its shareholders. In addition, if a non- U. S. corporation owns at least one U. S. subsidiary, under current law, any current non- U. S. subsidiaries and any future newly formed or acquired non- U. S. subsidiaries of the non- U. S. corporation will be treated as CFCs, regardless of whether the non- U. S. corporation is treated as a CFC. Subpart F income generally includes dividends, interest, rents, royalties, gains from the sale of securities and income from certain transactions with related parties. In addition, a Ten Percent Shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain. A non- U. S. corporation generally will be classified as a CFC for U. S. federal income tax purposes if Ten Percent Shareholders own, directly or indirectly, more than 50 % of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A " Ten Percent Shareholder " is a United States person (as defined by the Code) who owns or is considered to own 10 % or more of the value or total combined voting power of all classes of stock entitled to vote of such corporation. We do not believe that we were a CFC in ~~2023~~ **2024** , and we do not expect to be a CFC in ~~2024~~ **2025** . The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. An individual that is a Ten Percent Shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a Ten Percent Shareholder that is a U. S. corporation. Failure to comply with CFC reporting obligations may subject a United States shareholder to significant monetary penalties. We cannot provide any assurances that we will furnish to any Ten Percent Shareholder information that may be necessary to comply with the reporting and tax paying obligations applicable under the CFC rules of the Code. U. S. Holders should consult their own tax advisors with respect to the potential adverse U. S. tax consequences of becoming a Ten Percent Shareholder in a CFC. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, testing required to be conducted by us in connection with Section 404 of the Sarbanes- Oxley Act, and any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Deficient internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ADSs. If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs. Implementing any appropriate changes to our internal controls, including changes relating to our application of the requirements of Section 404 of the Sarbanes- Oxley Act, may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to continue to discover and develop novel

immunotherapeutics and vaccines for the treatment and prevention of infectious diseases, immunetolerance and cancer. We ~~previously identified material weaknesses in connection with our internal control over financial reporting. Although we have taken steps to remediate these material weaknesses, we may identify other material weaknesses in the future, which could have a significant adverse effect on our business and the trading price of our ADSs. For the year ended December 31, 2023, pursuant to Section 404 of the Sarbanes- Oxley Act, we are required to furnish a report by our senior management on our internal control over financial reporting. This report is required to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, while we remain an non- accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes- Oxley Act, we have been engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially continue to engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Management previously reported, in our Annual Report for the year ended December 31, 2022, material weaknesses in our internal control over financial reporting related to: (i) our IT general control environment has not been sufficiently designed to include appropriate controls over program development, program changes, computer operations and user access rights and (ii) policies and procedures with respect to the review, supervision and monitoring of our accounting and reporting functions were either not designed and in place or not operating effectively. During fiscal years 2022 and 2023, we undertook efforts to remediate previously disclosed material weaknesses, implement a company- wide formal control program, and strengthen our internal controls. Implementing Section 404 of the Sarbanes- Oxley Act within our environment has been a significant undertaking. Although management has concluded that the actions taken to strengthen our internal control over financial reporting, as well as the results of our testing over the design and operating effectiveness of these controls, remediated the previously identified material weaknesses as of December 31, 2023, there is no guarantee that our internal control over financial reporting will be effective in the future periods and the effectiveness of our internal controls are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with applicable policies, processes and documentation requirements may deteriorate. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our ADSs. We~~ could be subject to securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. The United Kingdom' s withdrawal from the ~~EU~~ **European Union** could increase the regulatory burden of product development and authorization in the United Kingdom and European Union. **The** ~~On June 23, 2016, a majority of voters in the United Kingdom voted in favor of the United Kingdom withdrawing from the European Union in a national referendum, commonly referred to as Brexit, and the~~ United Kingdom formally left the European Union on **31** January ~~31,~~ 2020 ~~. There~~ **(commonly referred to** ~~was~~ **as Brexit)** ~~a transition period during which EU pharmaceutical laws continued to apply to the United Kingdom, which expired on December 31, 2020~~ . **The European Union** ~~However, the EU~~ and the United Kingdom have concluded a **trade and cooperation agreement (“** TCA **”)** which ~~was provisionally applicable since January 1, 2021 and~~ has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not ~~foresee~~ **provide for** wholesale mutual recognition of the United Kingdom and European Union pharmaceutical regulations. ~~At present~~ **As a result** , **a separate application** ~~Great Britain has implemented EU legislation on the marketing, promotion, and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns in the most~~ **must be made to conduct a clinical trial in** ~~part with EU regulations, however it is possible that these~~ -- **the** ~~regimes will diverge in future now that Great Britain' s regulatory system is independent from the EU and the TCA does not provide for mutual recognition of~~ United Kingdom ~~and European Union pharmaceutical legislation. For example, the new Clinical Trials Regulation which became effective in the EU on January 31, 2022 and provides for a streamlined clinical trial application and assessment procedure covering multiple European Union Member States has not been implemented into the United Kingdom law, and a separate application will need to be submitted for clinical trial authorization in the United Kingdom. The cumulative effects of the disruption to the regulatory framework may add to the development lead time to marketing authorization and commercialization of products in the European Union and / or the United Kingdom. It is possible that there will be increased regulatory complexities which can disrupt the timing of our clinical trials and regulatory approvals. In addition, changes in, and legal uncertainty with regard to, national and international laws and regulations may present difficulties for our clinical and regulatory strategy. In addition, as a result of Brexit, other European Union Member States may seek to conduct referenda with respect to their continuing membership with the European Union. Given these possibilities and others we may not anticipate,~~ as well as the ~~absence of comparable precedent, it~~ **European Union and a separate U. K. marketing authorization** is **required to commercialize a medicinal product in** ~~unclear what financial, regulatory and legal implications the withdrawal of~~ the United Kingdom ~~from~~ **as well as** the European Union **. Obtaining such regulatory approvals is a lengthy and expensive process and this therefore adds time and expense to the conduct of our business in both the United Kingdom and European Union. In addition, the United Kingdom is seeking to reform aspects of the medicines legislation following its departure from the European Union. For example, on December 12, 2024, the U. K. government introduced a**

legislative proposal that, if implemented, will **replace** ~~have in~~ the ~~long- term~~ **current regulatory framework for clinical trials in the United Kingdom. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials** and **the development of medicinal products in the United Kingdom and / or European Union, our development plans may be impacted. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize** the full ~~extent to which~~ **market potential of our product candidates will be harmed and** our business ~~could~~ **, financial condition, results of operations and prospects will** be adversely affected.