**Risk Factors Comparison 2025-03-20 to 2024-03-28 Form: 10-K**

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The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward- looking statements we have made in this Annual Report on Form 10- K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10- K and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. Risks Related to our Financial Position and Capital Needs Our financial condition raises substantial doubt regarding our ability to continue as a going concern. Our consolidated financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. Based on our current operating plans and excluding any contribution from **future** revenues or external financing, however, we believe that our existing cash and cash equivalents will not be sufficient to fund our operating expenses and capital expenditure requirements for more than one year from the issuance of the consolidated financial statements for the year ended December 31, ~~2023. Specifically, based on our current operating plans and excluding any contribution from revenues or external financing, we believe these funds will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of~~ 2024. As a result, we have determined that there is substantial doubt regarding our ability to continue as a going concern, and our independent registered public accounting firm has included in its audit opinion for the year ended December 31, ~~2023~~ **2024** , an explanatory paragraph about such substantial doubt regarding our ability to continue as a going concern. The substantial doubt regarding our ability to continue as a going concern may adversely affect our stock price and our ability to raise capital necessary to execute our current operating plans. If we are unable to obtain additional capital, we may not be able to continue our operations on the scope or scale as currently conducted, and that could have a material adverse effect on our business, results of operations, financial condition, and ability to operate as a going concern. We have incurred significant losses since our inception **and are highly dependent on the commercial success of PEMGARDA for the foreseeable future** . We may **not** ~~continue to incur losses and may never~~ achieve or maintain profitability. Since our inception, we have incurred significant losses, and we may continue to incur significant expenses and operating losses for the foreseeable future. Our net losses were $ **169. 9 million and $** 198. 6 ~~million and $ 241. 3~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~732~~ **902** . ~~1~~ **0** million. Since our inception, we have financed our operations primarily with net proceeds from several public and private offerings of our capital stock. ~~In~~ **After receiving EUA in** March 2024, we ~~received an EUA~~ **have also funded our operations** from **sales of** ~~the FDA for~~ PEMGARDA, but have no other products authorized or approved for commercialization ~~and have not yet generated any revenue from product sales to date~~ . We may continue to incur significant expenses and operating losses. Our net losses may fluctuate significantly from quarter to quarter and year to year. Our expenses could increase substantially as we: • **continue to** commercialize PEMGARDA **; • advance the development of VYD2311** ; • initiate and conduct clinical trials of our product candidates; • develop product candidates in new indications or patient populations; • advance our preclinical and discovery programs, including development and screening of additional antibodies; • seek regulatory authorization or approval for any product candidates that successfully complete clinical trials; • pursue regulatory authorizations or approvals and coverage and reimbursement for our product candidates, if authorized or approved; • acquire or in- license other product candidates, intellectual property and / or technologies; • validate our commercial- scale cGMP manufacturing processes, and manufacture material under cGMP at our contracted manufacturing facilities for clinical trials and potential commercial sales; • maintain, expand, enforce, defend and protect our intellectual property portfolio; • comply with regulatory requirements established by the applicable regulatory authorities; • maintain and expand a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory authorization or approval; • hire and retain personnel, including research, clinical, development, manufacturing quality control, quality assurance, regulatory, scientific, and other personnel; and • incur additional legal, accounting and other expenses in operating as a public company. ~~Although we have received an EUA from the FDA for PEMGARDA, to date, we have not yet generated any revenue from product sales.~~ Our ability to execute our current business strategy and become and remain profitable is heavily dependent on **the commercial success of PEMGARDA for the foreseeable future and** our ability to develop and commercialize **other** product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities on a timeline that keeps pace with viral evolution, including completing preclinical testing and clinical trials of our product candidates, validating manufacturing processes, obtaining regulatory authorization or approval, and manufacturing, distributing, marketing, and selling any products for which we obtain regulatory authorization or approval, as well as discovering and developing additional product candidates. ~~We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.~~ Because of the numerous risks and uncertainties associated with product candidate development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability ~~. If we are required by regulatory authorities to perform clinical trials or preclinical studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase~~ . Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress

the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product authorizations or approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We have a limited operating history and ~~no history of~~ **limited experience with** commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability. We are a biopharmaceutical company with a limited operating history. We commenced operations in June 2020, and our operations to date have been largely focused on organizing and staffing, building an intellectual property portfolio, business planning, conducting research and development, establishing and executing arrangements with third parties for the manufacture of our product candidates, and capital raising. **Our recent focus has been and will continue to be supporting the commercialization of PEMGARDA, advancing VYD2311 as our next generation mAb candidate for COVID- 19, and establishing streamlined development pathways that could enable us to efficiently introduce new mAb candidates targeting SARS- CoV- 2.** To date, we have received regulatory authorization for only one product candidate, PEMGARDA, which received an EUA from the FDA in March 2024 ~~and which we are currently focused on commercializing~~ **for pre- exposure prophylaxis of COVID- 19** in ~~the U~~ **certain immunocompromised patients** . **It is uncertain as to if** ~~S. We have not historically demonstrated our~~ **or when** ~~ability to successfully conduct sales and marketing activities necessary for commercialization, and~~ we may ~~not~~ be successful in ~~doing so~~ **expanding the authorized use of PEMGARDA, if ever** . ~~Additionally~~ **Furthermore** , it is uncertain as to if or when we may submit ~~a request for~~ an ~~EUA or~~ application for regulatory **authorization or** approval for any other product candidate, and we may not be successful in receiving any such **additional** ~~EUA or~~ regulatory **authorization or** approval. 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 **or commercial** history ~~or a history of successfully developing and commercializing products~~ . In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors ~~. Having received an EUA from the FDA for PEMGARDA, we are transitioning from a company with a research and clinical focus to a commercial company, and we may not be successful in such a transition~~ . We will require additional funding through a combination of contribution from revenues, equity offerings, government or private- party grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements to ~~finance~~ **support** our ~~future~~ **continuing** operations **and pursue our growth strategy** . If we are unable to secure additional funding when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy. Our operations have consumed substantial amounts of cash since inception, and, although we received an EUA from the FDA for PEMGARDA in March 2024, we may continue to incur significant expenses and operating losses as we continue to develop our product candidate pipeline ~~and build out our manufacturing capabilities for our product candidates, which, if authorized or approved, may not achieve commercial success~~ . Aside from any revenue generated from sales of PEMGARDA, additional revenue, if any, will be derived from sales of products that may not be commercially available for a number of years, if at all. Furthermore, even if we obtain regulatory authorization **to expand the authorized use of PEMGARDA or if we obtain regulatory authorization** or approval for ~~a~~ **another** product candidate that we develop ~~, such as PEMGARDA,~~ or otherwise acquire, we may incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Accordingly, until such time, if ever, as we can generate substantial revenue from **PEMGARDA or** sales of **any future** authorized or approved ~~products~~ **product** , we expect to finance our operations through a combination of equity offerings, government or private- party ~~funding or~~ grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements. As of December 31, ~~2023~~ **2024** , we had cash and cash equivalents of $ ~~200~~ **69** . ~~6~~ **3** million ~~. Based on our current operating plans and excluding any contribution from revenues or external financing, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect~~ . We plan to use our cash and cash equivalents to fund research and development, manufacturing supply and commercialization costs for our product candidates, the development of additional programs in our pipeline and for working capital and other general corporate purposes. The timing and amount of our funding requirements will depend on many factors, including: • the revenue received from sales of PEMGARDA and any other product candidates for which we receive future regulatory authorization or approval; • the rate of progress in the development of our product candidates **, such as VYD2311** ; • the scope, progress, results and costs of discovery, nonclinical studies, preclinical development, laboratory testing and clinical trials for our product candidates and associated development programs; • the extent to which we develop, in- license or acquire other product candidates, intellectual property and / or technologies; • the scope, progress, results and costs of manufacturing and validation activities associated with our current product candidates and with the development and manufacturing of our future product candidates as we advance them through preclinical and clinical development; • the number and development requirements of product candidates that we may pursue; • the costs, timing and outcome of regulatory review of our product candidates; • our headcount growth and associated costs as we expand our research and development capabilities and build and maintain a commercial infrastructure for product candidates for which we obtain regulatory authorization or approval; • the timing and costs of securing sufficient manufacturing capacity for clinical and commercial supply of our product candidates, or the raw material components thereof; • the costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive regulatory authorization or approval; • the costs necessary to obtain regulatory authorizations or approvals, and the costs of post- marketing studies that could be required by regulatory authorities in jurisdictions where authorization or approval is obtained; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims; • the continuation of our existing licensing and collaboration arrangements and entry into new collaborations and licensing arrangements, if at all; • the ~~need and ability to hire and retain additional research, clinical,~~

~~development, scientific and manufacturing personnel; • the~~ costs we incur in maintaining business operations; • the need to implement additional internal systems and infrastructure; • the effect of competing technological, product and market developments; • the costs of operating as a public company; and • the impact of any business interruptions to our operations or to those of our third- party contractors resulting from any public health crisis. We may require additional capital to achieve our business objectives. In December 2023, we entered into a Controlled Equity OfferingSM Sales Agreement (the " Sales Agreement ") with Cantor Fitzgerald & Co., as sales agent (" Cantor "), pursuant to which we may, at our option, offer and sell up to an aggregate amount of $ 75. 0 million of our common stock, through Cantor, acting as sales agent. To date, we have sold 9, 000, 000 shares of our common stock under the Sales Agreement, resulting in net proceeds of $ 39. 3 million. Funds additional to the proceeds we may raise under the Sales Agreement may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long- term business strategy. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, including higher inflation rates, changes in interest rates and the recent disruptions to and volatility in the credit and financial markets in the U. S. and worldwide. If we are unable to secure additional funding when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial revenue from sales of authorized or approved products, such as PEMGARDA, ~~which received an EUA from the FDA in March 2024,~~ we expect to finance our operations through a combination of equity offerings, government or private- party ~~funding or~~ grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements. We do not currently have any other committed external source of funds. To the extent that we raise additional capital through the sale of equity, including pursuant to our existing Sales Agreement with Cantor, or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. **Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.** If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Risks Related to the Development of our Product Candidates Newly emerging and future SARS- CoV- 2 variants could reduce the activity and effectiveness of ~~antibodies~~ **mAbs** as a potential prevention of or treatment for symptomatic COVID- 19, which may significantly and adversely affect our ability to complete our clinical trials and to obtain and maintain authorization or approval of, and commercialize our product candidates. Our primary focus since inception has been the development of antibodies against COVID- 19. Multiple variants of the virus that ~~cause~~ **causes** COVID- 19 have been documented in the U. S. and globally, and newly emerging and future SARS- CoV- 2 variants could reduce the activity and effectiveness of ~~antibodies~~ **mAbs** as a potential prevention of or treatment for symptomatic COVID- 19, which may significantly and adversely affect our ability to complete our clinical trials and to obtain and maintain authorization or approval of, and commercialize our product candidates. For example, although preclinical studies showed that adintrevimab had the potential to broadly neutralize SARS- CoV- 2 and the previously predominantly circulating variants, including Alpha, Beta, Delta, and Gamma, in vitro analyses to evaluate neutralizing activity of adintrevimab against the Omicron variant and its sublineages generated data showing reduced neutralizing activity of adintrevimab against the Omicron BA. 1 and BA. 1. 1 sublineages compared to a reference strain and a lack of neutralizing activity against Omicron BA. 2. As a result, we paused enrollment in adintrevimab' s Phase 2 / 3 trials in January 2022, which were subsequently closed, and we paused submission of an EUA request. While we intend to continue to monitor the evolution of SARS- CoV- 2 and the in vitro activity of adintrevimab against predominant variants in the U. S. to identify a potential opportunity for an EUA request, we cannot be certain that adintrevimab will neutralize future variants and that we will submit an EUA for adintrevimab or whether an EUA will be granted if we do submit such request. PEMGARDA, which received an EUA from the FDA in March 2024, is an engineered version of adintrevimab, which we modified to improve binding to the Omicron variant and its sublineages. ~~The EUA of~~ PEMGARDA ~~was based on~~ **is authorized for use only when** the ~~totality~~ **combined national frequency** of ~~scientific evidence available~~ **variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90 %. To date, PEMGARDA has demonstrated in vitro neutralizing activity against major SARS- CoV- 2 variants** , including ~~data showing that the calculated serum neutralizing antibody titers against~~ JN. 1 ~~were consistent with the titer levels associated with efficacy in prior clinical trials of adintrevimab~~ , ~~the parent mAb for pemivibart~~ **KP. 3. 1. 1** , **XEC** and **LP. 8. 1** ~~other mAbs that were previously authorized for EUA~~ . However, newly emerging and future SARS- CoV- 2 variants could reduce the neutralizing activity and effectiveness of PEMGARDA. If this were to occur, the FDA may revise or revoke the EUA for PEMGARDA ~~based on any such reduction in neutralizing activity or effectiveness of PEMGARDA~~ , which would adversely affect our commercial prospects, and our ability to generate revenues from PEMGARDA may be limited or lost ~~. PEMGARDA is our first mAb in a planned series of innovative mAb candidates designed to keep pace with SARS- CoV- 2 viral evolution~~ . As the SARS- CoV- 2 virus evolves over time, we anticipate ~~leveraging our INVYMAB platform approach to~~ periodically ~~introduce~~ **introducing** new ~~or engineered~~ mAb candidates. ~~We expect that~~ **In January 2024, we nominated** VYD2311, a mAb optimized for neutralization potency against ~~recent~~ SARS- CoV- 2 lineages such as BA. 2. 86 and JN. 1, **as a drug candidate**

~~will be the next pipeline program to advance into clinical development~~ . Based on in vitro analyses, we believe such modifications may be able to enhance neutralization potency against current and future novel variants, but such efforts may not be successful against newly emerging or future variants, in order to support ~~an EUA or~~ regulatory **authorization or** approval of VYD2311. Additionally, it is possible that in vivo analyses ~~undertaken in the future~~ may not be consistent with in vitro analyses. New SARS- CoV- 2 variants could be less susceptible to such modifications and their mechanisms of action, or the results shown in preclinical studies may not be replicated in clinical trials. Additionally, it is possible that even if a product candidate showed in vitro neutralizing activity against the predominant SARS- CoV- 2 variant at the initiation of a clinical trial, the predominant circulating variant may evolve and neutralizing activity of the candidate become reduced or negligible during the course of a clinical trial or at the time of our planned ~~EUA~~ **submission** ~~or~~ **for** ~~other~~ regulatory ~~submission~~ **authorization or approval** . Further, we may not be able to address reductions in neutralization potency with adjustments to the dose or dosing frequency. This would significantly and adversely affect our ability to complete our clinical trials, obtain and maintain authorization or approval of and commercialize VYD2311 or any future product candidates. In addition, if our planned dosing of a product candidate were to be increased in response to reduction in neutralizing activity against dominant circulating SARS- CoV- 2 variants or for other reasons, it could impact drug supply and pricing, which could adversely affect our commercial prospects. Even if we obtain authorization or approval, such authorization or approval may be revised or revoked based on changes in circulating variants that reduce the neutralizing activity or effectiveness of our product candidates. To date, we have received regulatory authorization for only one product candidate, PEMGARDA. ~~All of our other product candidates, other than adintrevimab, are currently in preclinical development.~~ If we are unable to successfully develop, receive and maintain an EUA or regulatory approval for and commercialize our product candidates for the indications we seek, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed. To date, we have received regulatory authorization for only one product candidate, PEMGARDA, which has not been approved, but has been authorized for emergency use by the FDA under an EUA ~~,~~ **only** for pre- exposure prophylaxis of COVID- 19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg). We currently have no other products approved or authorized for sale **. In July 2024** , ~~and all~~ **we submitted a request to the FDA to expand the existing EUA for PEMGARDA to cover treatment** of **mild- to- moderate COVID- 19 in certain immunocompromised patients, which request was denied by the FDA in February 2025. While we have submitted a response requesting that the FDA reconsider our EUA amendment request for treatment, we cannot be certain if** ~~our~~ **or when** ~~other~~ **the** ~~product candidates~~ **FDA may do so** , **or** ~~other~~ **the** ~~than adintrevimab, are currently in preclinical development~~ **outcome of any further engagement with the FDA regarding such request** . Adintrevimab is an investigational mAb that we previously advanced into global Phase 2 / 3 trials for the prevention and treatment of COVID- 19. We reported preliminary safety and efficacy data (pre- Omicron) for both trials in March 2022. However, based on feedback from the FDA regarding adintrevimab' s lack of neutralizing activity against the Omicron BA. 2 variant, we paused the submission of an EUA request and we have closed such trials. Although we intend to monitor the evolution of SARS- CoV- 2 and the in vitro activity of adintrevimab against predominant variants in the U. S. to identify a potential opportunity for an EUA request for adintrevimab in the event of a susceptible variant, we cannot be certain that adintrevimab will neutralize future variants and that we will submit an EUA for adintrevimab or whether an EUA will be granted if we do submit such request. ~~We anticipate that~~ **In January 2024, we nominated** VYD2311, a **next generation** mAb ~~optimized~~ **candidate** for **COVID** ~~neutralization potency against recent SARS~~ - **19,** ~~CoV- 2 lineages such~~ as **a drug candidate,** ~~BA. 2. 86~~ and ~~JN.~~ **in February 2025, we announced completion of recruitment in our Phase** 1 ~~, will be the next pipeline program to advance into~~ clinical ~~development~~ **trial of VYD2311, as well as positive clinical data for both safety and pharmacokinetics** ; however, we cannot be certain of the ~~potential~~ **future** development, regulatory or commercialization timelines of such product candidate. Our ability to generate revenue from our future product candidates will depend heavily on ~~the successful~~ **successfully completing** development, **obtaining** regulatory **authorization or** approval ~~or granting of EUA for the prevention and / or treatment of COVID- 19~~ , obtaining ~~of~~ manufacturing supply, capacity and expertise **,** and ~~eventual~~ **eventually** ~~commercialization~~ --- **commercializing** ~~of~~ our product candidates ~~. In the absence of an EUA declaration and determination issued under the FDCA, we will not be able to receive an EUA~~ . The success of PEMGARDA **, VYD2311** or any other product candidates that we develop or otherwise may acquire will depend on many factors, including: • the status of new or emerging SARS- CoV- 2 variants and whether such SARS- CoV- 2 variants reduce the neutralizing activity and effectiveness of PEMGARDA **, VYD2311** or any other mAb candidates we may develop, and whether we are successful in timely identifying new mAb candidates that mitigate the risk of reduced neutralizing activity and effectiveness against future SARS- CoV- 2 variants; • the continuing need for therapies for the prevention and treatment of COVID- 19, including as a result of the development of COVID- 19 into an endemic disease ~~or~~ **, and** the ~~inability~~ **existence** of **any** other available therapies ~~to~~ **that** effectively ~~address~~ **prevent or treat** COVID- 19 **in the populations targeted by our product candidates** ; • the timing and progress of our discovery, nonclinical, and clinical development activities; • the number and scope of nonclinical and clinical programs we decide to pursue; • our ability to successfully work with the FDA or other regulatory authorities to establish streamlined development pathways that would allow us to ~~fully leverage our INVYMAB platform approach to~~ efficiently **periodically** introduce new ~~or engineered~~ mAb candidates targeting SARS- CoV- 2; • filing acceptable IND applications with the FDA or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates; • our ability to **align** ~~reach agreement~~ with the FDA or other regulatory authorities as to the design or implementation of our clinical trials, including the use of a correlate of protection (surrogate of clinical efficacy) in an immunobridging approach to a pivotal clinical trial; • **our ability to align with the FDA or other regulatory authorities on the data required to support the regulatory authorization or approvals that we seek for our product candidates, particularly in light of the FDA' s discretion with respect to EUAs in the U. S. in making its determination about whether, based on the totality of scientific evidence available, the known and potential benefits of a product candidate**

**outweigh the known and potential risks; •** the sufficiency of our financial and other resources to complete the necessary nonclinical studies and clinical trials, manufacture ~~the~~ **our** product candidates and complete associated regulatory activities; • our ability to establish and maintain agreements ~~with third- party manufacturers and suppliers~~ for clinical **and commercial** supply ~~for~~ **of** our ~~clinical trials~~ **product candidates,** and **to** ~~commercial manufacturing and~~ successfully develop, obtain regulatory authorization or approval for, and ~~then successfully~~ commercialize our product candidates; • successful enrollment and timely completion of clinical trials, including our ability to generate positive data from any such clinical trials; • the costs associated with the discovery and development of any additional ~~development programs and~~ product candidates we identify in- house or acquire through collaborations; • timely receipt of **regulatory** authorizations or approvals ~~from applicable regulatory authorities~~, and the scope and duration of any emergency use authorization received, such as the EUA for PEMGARDA; • developing and expanding sales, marketing and distribution capabilities and commercializing products, if authorized or approved, whether alone or in collaboration with others; • our ability to secure and maintain required state licenses for distribution of our products, if authorized or approved, or other distribution disruptions; • acceptance of the benefits and use of our products, including method of administration, if authorized or approved, by patients, the medical community and third- party payors, for their authorized or approved indications; • the prevalence and severity of adverse events experienced with our product candidates; • the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any product candidate that we develop; • ~~the availability and sufficiency of government funding for the purchase and / or reimbursement of products for the diagnosis, prevention and treatment of COVID- 19; •~~ our ability to obtain and maintain third- party coverage and adequate reimbursement for our product candidates, if authorized or approved, and the extent to which patients **are** ~~will be~~ willing to pay out- of- pocket for such products, in the absence of such coverage or reimbursement ~~for all or part of the cost~~; • the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder; • our ability to obtain and maintain patent, trademark and trade secret protection and regulatory exclusivity for our product candidates if approved, and otherwise protecting our rights in our intellectual property portfolio; • our ability to maintain compliance with regulatory requirements, cGCP, cGLP, and cGMP, and to comply effectively with other rules, regulations and procedures applicable to the development and sale of pharmaceutical products; • potential significant and changing government regulation, regulatory guidance and requirements and evolving treatment guidelines; • our ability to maintain a continued acceptable safety, tolerability and efficacy profile of products following any authorization or approval; and • the impact of any business interruptions to our operations or those of third parties with which we work, including as a result of any public health crisis. 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 PEMGARDA or any other product candidates that we develop or otherwise may acquire, which would materially harm our business. If we do not **maintain regulatory authorization for PEMGARDA or** receive **and maintain regulatory** authorization or approval for any future product candidates we develop or otherwise may acquire, we may not be able to continue our operations. Because our product candidates represent novel approaches to the prevention and / or treatment of a relatively new disease, there are many uncertainties regarding the development, market acceptance, third- party reimbursement coverage **,** and commercial potential of our product candidates. We may not be successful in aligning with regulators on an expedited and replicable pathway to SARS- CoV- 2 mAb authorization or approval. COVID- 19 is a relatively new disease, and the prevention and treatment of this disease is evolving. Another party may be successful in producing a more efficacious prophylaxis or treatment for COVID- 19, which may make it more difficult for us to obtain funding or lead to decreased demand for our product candidates. ~~Many~~ **Other** small and large companies ~~are~~ **may be** developing therapies for the prevention and / or treatment of COVID- 19, including antibodies, vaccines, antivirals, and other products. Some of these are being marketed and others are further along in the development and commercialization process than we are and several of these companies have access to larger pools of capital, including government funding, and broader infrastructure that may make them more successful at developing, manufacturing or commercializing their products for the prevention and / or treatment of COVID- 19. The success or failure of other companies, or perceived success or failure, may impact our ability to obtain future funding or to successfully commercialize our product candidates for COVID- 19 prevention and / or treatment. As of the date of this report, no mAb has been approved in the U. S. for prevention (pre- or post- exposure) or treatment of COVID- 19. Other than the EUA for PEMGARDA issued by the FDA in March 2024, the FDA previously issued an EUA for tixagevimab / cilgavimab for pre- exposure prophylaxis of COVID- 19, in addition to EUAs for casirivimab / imdevimab and bamlanivimab / etesevimab for post- exposure prophylaxis of COVID- 19 in certain individuals. In addition, four mAb products, casirivimab / imdevimab, bamlanivimab / etesevimab, sotrovimab, and bebtelovimab received an EUA from the FDA for the treatment of COVID- 19 in patients at high risk of disease progression. However, the clinical utility of these products has varied over time due to the emergence of SARS- CoV- 2 variants demonstrating partial or full resistance to neutralization and at this time none of these products, other than PEMGARDA, are authorized for use in prevention or treatment of COVID- 19 in the U. S. due to loss of activity as new variants emerged. Because the use of ~~engineered~~ mAbs is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement and the commercial potential for our product candidates. In pursuing, and eventually obtaining, an EUA for PEMGARDA in the U. S., we aligned with the FDA on a primary efficacy analysis for our CANOPY Phase 3 pivotal clinical trial that used a correlate of protection (surrogate of clinical efficacy) in an immunobridging approach comparing data obtained in the CANOPY clinical trial to certain historical data from our previous Phase 2 / 3 clinical trial of adintrevimab for the prevention of COVID- 19 (EVADE). Based on FDA feedback, the use of a correlate of protection in an immunobridging approach to a pivotal EUA- directed clinical trial may be a reasonable approach for a new mAb candidate when clinical trial data from a " prototype " mAb is available and the new mAb candidate satisfies certain criteria. We continue to engage with the FDA with the aim of establishing expedited and replicable pathways for the authorization or approval of new ~~or engineered~~ SARS- CoV- 2 mAbs ~~that emerge from our INVYMAB platform approach~~. We

expect that these discussions with the FDA will continue as we advance VYD2311, ~~a~~ **our next generation** mAb **candidate for COVID- 19** ~~developed using our INVYMAB platform approach~~. However, there can be no assurance of the outcome of these discussions, that VYD2311 or any future product candidates will meet the necessary criteria to leverage the same ~~pathway to a potential~~ **criteria that supported the PEMGARDA** EUA ~~as PEMGARDA~~ or as to the length of the clinical trials, the number of patients the FDA or other comparable foreign regulatory authorities will require to be enrolled in the clinical trials, or that the design of or data generated in the clinical trials will be acceptable to the FDA or other comparable foreign regulatory authorities to support EUA **authorization or BLA approval**, or similar authorization **or approvals** outside of the U. S ~~., or marketing approval~~. In addition, the FDA or other comparable foreign regulatory authorities may take longer than usual to come to a decision on any request for authorization or approval that we submit and may ultimately determine that there is insufficient data, information or experience with our product candidates to support an authorization or approval decision. **For example, in July 2024, we submitted a request to the FDA to expand the existing EUA for PEMGARDA to cover treatment of mild- to- moderate COVID- 19 in certain immunocompromised patients, and thereafter we provided the FDA with updates as the SARS- CoV- 2 virus evolved and we generated data for new variants as part of our ongoing industrial virology effort. The EUA process in the U. S. does not rely on a statutory timeline such as the timelines embedded into PDUFA- based regulatory actions such as a BLA approval process, and the FDA has discretion with respect to EUAs in making its determination about whether, based on the totality of scientific evidence available, the known and potential benefits of a product candidate outweigh the known and potential risks. In February 2025, the FDA declined our EUA amendment request. While we have submitted a response requesting that the FDA reconsider our EUA amendment request for treatment, we cannot be certain if or when the FDA may do so, or the outcome of any further engagement with the FDA regarding such request.** The FDA or other comparable foreign regulatory authorities may also require that we conduct additional post- marketing studies or implement risk management programs, such as REMS, until more experience with our product candidates is obtained. Finally, after increased usage, we may find that our product candidates do not have the intended effect or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory authorization or approval and commercial prospects. The success of our business depends largely upon our ability to ~~rapidly and perpetually~~ develop ~~engineered~~ **and periodically introduce new** mAbs that can broadly neutralize SARS- CoV- 2, SARS- CoV and additional pre-emergent coronaviruses. ~~We~~ **Beyond PEMGARDA, which is currently authorized only for pre- exposure prophylaxis of COVID- 19 in certain immunocompromised patients, we** may fail to deliver **future** mAbs that effectively prevent or treat symptomatic COVID- 19. Even if we are able to identify and develop such mAbs, we cannot ensure that such product candidates will achieve **regulatory** authorization or approval ~~to safely and effectively prevent or treat symptomatic COVID- 19 or other future coronavirus diseases~~, or achieve commercial success, even if authorized or approved. If we uncover any previously unknown risks related to our mAbs, or if we experience unanticipated expenses, problems or delays in developing our product candidates, we may be unable to achieve our strategy ~~of leveraging our INVYMAB platform approach~~ to ~~rapidly~~ **continuously discover** and **engineer new candidates** ~~perpetually deliver antibody- based therapies~~ that **can be leveraged to keep pace with** ~~protect vulnerable people from the devastating consequences of circulating~~ viral ~~threats~~ **evolution**. Further, competitors who are developing products with similar technology may experience problems with their products that could identify problems that would potentially harm our business. There is no assurance that the approaches offered by our product candidates will gain broad acceptance among healthcare practitioners or patients or that governmental agencies or third- party medical insurers will be willing to provide reimbursement coverage for our product candidates. Since our product candidates represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend significant capital trying to obtain **regulatory** authorization or approval for product candidates that have an uncertain commercial market. The market for any products that we successfully develop will also depend on the **product profile, including the route of administration, and** cost of the product. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our products, we will not become profitable, which would materially and adversely affect the value of our common stock. **We** ~~In addition, our mAbs may be provided to patients in combination with other agents provided by third parties or by us. The cost of such combination therapy may increase the overall cost of therapy, which may affect our ability to obtain reimbursement coverage for the combination therapy from governmental or private third- party medical insurers. Our INVYMAB platform approach~~ may not produce durable, broadly neutralizing, effective or safe mAbs in an adequate time period to address a changing virus. If we are unable to timely identify, develop, obtain and maintain authorization or approval for, and commercialize mAbs ~~on~~ **in** a **manner** ~~perpetual basis~~ that keeps pace with viral evolution, our business prospects will be significantly harmed. PEMGARDA is ~~our~~ **the** first mAb in **our pipeline** ~~a planned series of innovative mAb candidates designed~~ to **receive regulatory authorization** ~~keep pace with SARS- CoV- 2 viral evolution~~. We anticipate leveraging our ~~INVYMAB~~ **integrated technology** platform ~~approach~~ to periodically introduce new ~~or engineered~~ mAb candidates. Our ~~INVYMAB~~ platform ~~approach~~ is designed to produce new ~~or engineered~~ mAb candidates that provide broad in vitro neutralization against past and current VoCs and their sublineages. However, we may not be successful in developing product candidates, or developing product candidates in an adequate time period, to target a changing virus. If we do develop product candidates, they may not be durable enough to increase the probability of providing a longer period of protection than other antibody solutions or be high- functioning and long- lasting with a high barrier to viral escape. If we are unable to timely identify, develop, obtain and maintain authorization or approval for, and commercialize mAbs ~~on~~ **in** a **manner** ~~perpetual basis~~ that keeps pace with viral evolution, our business prospects will be significantly harmed. Preclinical studies and clinical trials are expensive, time- consuming, difficult to design and implement, and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates. If we are not able to obtain and maintain required regulatory authorizations or approvals, we will not be able to successfully commercialize our product

candidates, and our ability to generate product revenue will be adversely affected. To date, we have received regulatory authorization for only one product candidate, PEMGARDA, which has not been approved, but has been authorized for emergency use by the FDA under an EUA ~~,~~ **only** for pre- exposure prophylaxis of COVID- 19 in certain **immunocompromised patients. VYD2311 is in Phase 1 clinical development** ~~adults and adolescent individuals (12 years of age and older weighing at least 40 kg)~~. All of our other product candidates, other than adintrevimab, are in preclinical development and their risk of failure is high. The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if authorized or approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U. S. and in other countries where we may test and market our product candidates. Before obtaining regulatory authorization to commercialize any of our product candidates, we must demonstrate through complex and expensive preclinical testing and clinical trials certain efficacy and safety requirements of the applicable regulatory agencies. For regulatory approval, we must demonstrate that our product candidates are both safe and effective for use in each target indication, typically requiring lengthy, large, well- controlled clinical studies. In particular, because our product candidates are subject to regulation as biological products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, authorization or approval policies, regulations or the type and amount of clinical data necessary to gain authorization or approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process, and we could encounter problems that cause us to abandon or repeat clinical trials. Even if our future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our product candidates for their targeted indications or support continued clinical development of such product candidates. Our current or future clinical trial results may not be successful. In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for authorization or approval. Moreover, results acceptable to support authorization or approval in one jurisdiction may be deemed inadequate by another regulatory authority to support ~~regulatory~~ authorization or approval in that other jurisdiction. To the extent that the results of ~~the~~ **our** trials are not satisfactory to the FDA or foreign regulatory authorities for support of an authorization or approval, we may be required to expend significant resources, which may not be available to us, to conduct additional preclinical studies or trials for our product candidates either prior to or post- authorization or approval, or they may object to elements of our clinical development program, requiring their alteration. Of the large number of products in development, only a small percentage successfully complete the FDA' s or comparable foreign regulatory authorities' approval processes and are commercialized. Even if we eventually complete clinical testing and receive authorization for emergency use or approval of a BLA or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post- market clinical trials. The FDA or the comparable foreign regulatory authorities also may authorize or approve for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory **authorization or** approval ~~or other marketing authorization~~ would delay or prevent commercialization of that product candidate and ~~would~~ adversely impact our business and prospects ~~. Furthermore, even if we obtain regulatory authorization or approval for our product candidates, we still need to build and maintain a commercial organization, establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from commercial and government payors, including government health administration authorities. If we are unable to successfully commercialize PEMGARDA or any of our future product candidates, we may not be able to generate sufficient revenue to continue our business~~. We have and may experience delays in beginning or conducting clinical trials or numerous unforeseen events before, during or as a result of clinical trials that could delay or prevent our ability to complete clinical trials, receive regulatory authorization or approval or commercialize our product candidates. We have and may again in the future experience delays in conducting clinical trials, and we do not know whether our clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. We may experience numerous unforeseen events before, during or after the conduct of our clinical trials that could delay or prevent our ability to complete such trials or receive regulatory authorization or approval for or commercialize our product candidates, or that could significantly increase the cost of such trials, including: • inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials; • delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials; • delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates; • delays in reaching agreement with the FDA or other regulatory authorities as to the design or implementation of our clinical trials, including the use of a correlate of protection (surrogate of clinical efficacy) in an immunobridging approach to a pivotal clinical trial; • delays in obtaining regulatory authorization to commence a clinical trial; • challenges in reaching an agreement on acceptable terms with clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites; • delays in obtaining IRB approval or Ethics Committees opinions at each trial site; • challenges in recruiting suitable patients to participate in a clinical trial; • challenges in having patients complete a clinical trial or return for post- treatment follow- up; • findings from inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold; • clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial, including as a result of changing standards of care or

the ineligibility of a site to participate; • failure to perform in accordance with the applicable regulatory requirements, including the FDA' s regulations and cGCP requirements, or applicable regulatory requirements in other countries; • addressing patient safety concerns that arise during the course of a trial, including the occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits; • the evolution of SARS- CoV- 2 variants during the course of a clinical trial may adversely impact the neutralizing activity of our product candidates and our ability to complete the trial if the potential benefits are no longer determined to outweigh the potential risks of any such product candidate as a result of reduced neutralizing activity against circulating SARS- CoV- 2 variants; • inability to recruit and / or successfully contract with a sufficient number of clinical trial sites; • difficulties in manufacturing sufficient quantities of product candidate for use in clinical trials, including as a result of supply chain challenges or otherwise; • suspensions or terminations by IRBs or Ethics Committees at the institutions where such trials are being conducted, by the independent Data Monitoring Committee for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above; • changes in regulatory requirements or guidance, or feedback from regulatory authorities that requires us to modify the design or conduct of our clinical trials; • 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 development programs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, especially if regulatory bodies require the completion of non- inferiority or superiority trials or the sample size needs to be increased based on the outcome rates observed during early trial conduct, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate; • enrollment in clinical trials may be impacted by the emergence of variants and rate of infection prevalence in the relevant communities, which can change once a trial is initiated; • the evolution of SARS- CoV- 2 variants during the course of a clinical trial may impact the prevalent variant of infection for patients at one or more sites and adversely impact enrollment potential; • the screen failure rate for clinical trials of our product candidates may be higher than we anticipate, requiring us to screen larger numbers of patients than originally planned; • the need to modify a trial protocol; • unforeseen safety issues; • emergence of dosing issues; • lack of effectiveness data during clinical trials; • changes in the standard of care of the indication being studied; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us 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; • we conducted our STAMP trial (evaluating adintrevimab for the treatment of COVID- 19) at sites outside of the U. S.; in the future, the applicable foreign regulatory authorities may determine that a placebo- controlled trial would expose patients to unacceptable health risks (because alternative effective therapies are or may become available in these regions during the conduct of the trial), which could delay enrollment of a trial and the authorization or approval of our products; • the cost of clinical trials of our product candidates may be greater than we anticipate, and we may not have funds to cover the costs; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may not be able to be procured or distributed as needed; • regulators may revise the requirements for authorizing or approving our product candidates, or such requirements may not be as we anticipate; and • any future collaborators that conduct clinical trials may face any of the above issues and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us. 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 and timely complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • incur unplanned costs; • be delayed or unsuccessful in obtaining authorization or approval for our product candidates; • obtain authorization or approval for indications or patient populations that are not as broad as intended or desired; • obtain authorization or approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings (such as for PEMGARDA) or REMS; • be subject to additional post- marketing testing requirements; • be subject to changes in the way the product is administered; or • have regulatory authorities withdraw or suspend their authorization or approval of the product or impose restrictions on its distribution after obtaining authorization or approval. We, the FDA, other regulatory authorities outside the U. S. or an IRB or Ethics Committees may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks, including, for example, because the predominant SARS- CoV- 2 variant in the country or clinical trial site is not susceptible to our product candidate, or if the FDA or other regulatory authorities outside the U. S. find deficiencies in our IND or similar application outside the U. S. or the conduct of the trial. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed or rendered impossible. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and authorization or approval process, and jeopardize our ability to commence product sales and generate revenues. **PEMGARDA has not been approved, but has been authorized for emergency use by the FDA under an EUA.** All of our product candidates will require extensive clinical testing before we would be in a position to submit a BLA to the FDA or MAA to the EMA for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for our product candidates and submit a BLA or MAA for regulatory approval of any of our product candidates, if at all, or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, EMA or other regulatory authorities on our clinical development program, and the FDA, EMA or other regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs. We cannot predict with any certainty whether or when we might complete a given clinical trial. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the

commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed or lost. In addition, any delays in our clinical trials could increase our costs, slow down the development and authorization or approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. 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 regulatory authorization or approval of our product candidates. There can be no assurance that the public health emergency in the U. S. declared under the FDCA permitting the FDA to authorize drugs and biologics for emergency use during the COVID- 19 pandemic will continue to be in place for an extended period of time and that the product candidates we are developing for COVID- 19 could be granted an EUA by the FDA or similar authorization by regulatory authorities outside of the U. S. if we decide to apply for such an authorization. If we do not apply for such an authorization or, if we do apply and no authorization is granted or, if once granted, such as the EUA for PEMGARDA, it is terminated or revoked, we will be unable to sell our product candidates in the near future and instead, would need to pursue the traditional regulatory approval processes of the FDA or comparable foreign authorities, which are lengthy, time consuming and inherently unpredictable, and which we may determine not to pursue. If we are not able to obtain ~~required~~ **or maintain** regulatory authorization or approval for our product candidates, our business will be substantially harmed. We also cannot guarantee how long it will take regulatory agencies to review our EUA requests, if submitted, for our product candidates. ~~On March 22, 2024, we~~ **PEMGARDA is our first and only product candidate that has** received **regulatory authorization. PEMGARDA is not approved, but has been authorized for emergency use by the FDA under** an EUA **only** ~~from the FDA~~ for ~~PEMGARDA~~ **pre- exposure prophylaxis of COVID- 19 in certain immunocompromised patients** . We may seek an EUA for future product candidates and may seek similar authorization from regulatory authorities outside of the U. S., such as conditional marketing authorization from the European Commission. If we apply for an EUA from the FDA and it is granted, such as the EUA for PEMGARDA, such EUA will authorize us to market and sell our COVID- 19 mAb in the U. S. under certain conditions of authorization as long as a public health emergency declared under the FDCA exists. The FDA may issue an EUA during a public health emergency declared under the FDCA if the agency determines that the known and potential benefits of a product outweigh the known and potential risks and if other regulatory criteria are met. Although we received an EUA from the FDA for PEMGARDA, there is no guarantee that we will apply for an EUA **or similar authorization** for adintrevimab, VYD2311 or any other product candidates ~~, or other similar authorization~~ or, if we do apply, that we will be able to obtain an EUA or such similar authorization. If an EUA or other authorization is granted ~~, such as the EUA from the FDA for PEMGARDA~~ , we will rely on the FDA or other applicable regulatory authority policies and guidance governing products authorized in this manner in connection with the marketing and sale of our product. If these policies and guidance change unexpectedly and / or materially or if we misinterpret them, potential sales of our product could be adversely impacted. Additionally, the FDA may terminate an EUA if safety issues or other concerns about our product, such as loss of neutralizing activity against dominant circulating SARS- CoV- 2 variants, arise or if we fail to comply with the conditions of authorization. **The** ~~Additionally, the~~ FDA has expected that companies that receive an EUA for COVID- 19 antibodies will pursue licensure of their products under a BLA. Unless streamlined development pathways are established **and / or expedited regulatory review and approval approaches are available** , we may not pursue a BLA for our product candidates for COVID- 19 given the evolving SARS- CoV- 2 variants, and if we determine not to pursue a BLA, this may adversely affect our ability to obtain or maintain an EUA in the U. S. On February 4, 2020, the Secretary of HHS determined pursuant to his authority under Section 564 of the FDCA that COVID- 19 represented a public health emergency with significant potential to affect national security or the health and security of U. S. citizens living abroad. Following this determination, on March 27, 2020, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID- 19 pandemic, subject to the terms of any authorization issued by the FDA. The EUA ~~request~~ for PEMGARDA was issued under this declaration. The Secretary of HHS may terminate this EUA declaration at any time. If the Secretary of HHS terminates an EUA declaration under the FDCA, then any EUAs issued based on that declaration will cease to be in effect, and FDA may no longer issue EUAs for products covered by that declaration. Accordingly, even if we apply and obtain an EUA from the FDA, such as the EUA for PEMGARDA, there is no guarantee of the duration for which we would be able to maintain it. The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID- 19 pandemic under Section 564 of the FDCA, unless the declaration is terminated or authorization revoked sooner. If we apply for an EUA or similar authorization from regulatory authorities outside of the U. S., the failure to obtain such authorization or the termination of such an authorization, if obtained, would adversely impact our ability to market and sell our **product candidate** ~~COVID- 19 antibody~~ , which could adversely impact our business, financial condition and results of operations. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable, and it 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, authorization or approval policies, regulations, and the type and amount of clinical data necessary to gain authorization or approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. Other than the EUA for PEMGARDA in the U. S. **for pre- exposure prophylaxis of COVID- 19 in certain immunocompromised patients** , we have not obtained regulatory authorization or approval for any other product candidate, and it is possible that we may never **be successful in expanding the authorized use of PEMGARDA or** obtain regulatory authorization or approval for any other product candidates in the future. Neither we nor any current or future collaborator is permitted to market any drug product candidates in the U. S. until we receive regulatory authorization with an EUA or approval of a BLA from the FDA, and we cannot market it in the European Union until we receive marketing authorization from the European Commission, or other required regulatory authorization or approval in other countries. If an existing EUA, such as the EUA for PEMGARDA, or

similar authorization from regulatory authorities outside of the U. S. is revised or revoked, we would be unable to sell our product candidate in the near future and instead, we would need to pursue the traditional regulatory approval processes of the FDA or comparable foreign regulatory authorities **. We may decide to pursue a BLA pathway (or the equivalent thereof in foreign jurisdictions) for full marketing approval of our product candidates** . Prior to obtaining approval pursuant to a traditional regulatory approval process to commercialize any drug product candidate in the U. S. or abroad, we must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidate is safe, pure and effective for its intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs. Our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or with our interpretation of data from preclinical studies or clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • we may be unable to collect sufficient data from clinical trials of our product candidates to support the submission and filing of a BLA with the FDA, MAA with the EMA or other submission; • we may fail bioresearch monitoring, FDA inspection or comparable foreign regulatory authorities' inspection; • we may fail an FDA or comparable foreign regulatory authorities' inspection of our third- party contract manufacturing or testing facilities for which we contract and test clinical and commercial supplies; • the FDA or comparable foreign regulatory authorities may find our contract manufacturing related activities (e. g., process validation, product characterization, product stability and expiry, and comparability establishment) insufficient for approval; and • the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval. **If we are unable to align with the FDA (or other regulatory authorities outside of the U. S.) on such a pathway beyond the EUA (or similar conditional marketing authorization outside of the U. S.) for our product candidates or, even if we align, if we fail to receive such full regulatory approval, our business may face challenges in achieving long- term market penetration.** In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay authorization or approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain, increase the costs of compliance or restrict our ability to maintain any regulatory authorizations or approvals we may have obtained **. Further, evolving or changing plans or priorities at the FDA or other regulatory bodies, including based on regulatory policy changes, such as those at U. S. agencies such as HHS, FDA, and the U. S. Centers for Disease Control due to the change in U. S. presidential administration in January 2025, may significantly impact our ability to obtain or maintain an EUA, including our EUA for PEMGARDA** . Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory authorization or approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large- scale clinical trials will be successful, nor does it predict final results. For example, we may be unable to identify suitable animal disease models for our product candidates, which could delay or frustrate our ability to proceed into clinical trials or obtain regulatory authorization or approval. Our product candidates may fail to show the desired safety and efficacy in clinical development despite having progressed through preclinical studies and initial clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in preclinical testing and earlier- stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory authorization or approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects. Interim, top- line, initial and preliminary results from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, top- line, initial or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top- line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between interim, top- line, initial or preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. 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, any top- line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Many companies in the pharmaceutical and

biotechnology industries have suffered significant setbacks in late- stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Further, others, including regulatory agencies 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 development 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 you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top- line, initial or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain authorization or approval for, and commercialize, our product candidates may be harmed, which could significantly harm our business prospects. Our preclinical studies and clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent, delay or limit the scope of regulatory authorization or approval of our product candidates, limit their commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates. To obtain the requisite regulatory authorizations or approvals to commercialize our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication for obtaining product approval, or meet the clinical or surrogate efficacy and the safety primary endpoints of the pivotal clinical trial (s) for an EUA (in addition to other regulatory requirements) towards obtaining an EUA. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved. We may fail to demonstrate with substantial evidence from adequate and well- controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and effective for their intended uses or otherwise meet requirements for an EUA. ~~For example, the clinical data available from the STAMP (evaluating adintrevimab for the treatment of COVID- 19) and EVADE (evaluating adintrevimab for the prevention of COVID- 19) trials may be insufficient to support a BLA or marketing authorization for adintrevimab, and we may not be able to generate additional data if the FDA or comparable foreign regulatory authorities require additional trials in support of a BLA or marketing authorization.~~ If our product candidates are associated with undesirable effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may decide or be required to perform additional preclinical studies or to halt or delay further clinical development of our product candidates or to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, which may limit the commercial use for the product candidate, if authorized or approved. Some side effects may not be appropriately recognized or managed by the treating medical staff, such as anaphylaxis that has been seen in the class of mAbs of which ADG20 **(adintrevimab)** and PEMGARDA are a part, and toxicities resulting from mAb therapy targeting an exogenous target, as with our product candidates, which can be nonspecific. Anaphylaxis has been observed with PEMGARDA. If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug, the FDA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications, or require that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates that we have not planned or anticipated. Side effects may also lead regulatory authorities to require stronger product warnings on the product label including boxed warnings or warnings and precautions, costly post- marketing studies, and / or a REMS, among other possible requirements. For example, PEMGARDA has been authorized with a boxed warning for anaphylaxis, which could impede our ability to successfully market and commercialize PEMGARDA and our ability to compete successfully against our competitors. Such findings could further result in regulatory authorities failing to provide authorization or approval for our product candidates or limiting the scope of the authorized or approved indication, if authorized or approved. Many product candidates that initially showed promise in early- stage testing have later been found to cause side effects that prevented further development of the product candidate. Even if we are able to demonstrate that any serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates and may harm our business, financial condition and prospects significantly. Additionally, if one or more of our product candidates receives authorization or approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may suspend, withdraw or limit authorizations or approvals of such product, or seek an injunction against its manufacture or distribution; • regulatory authorities may require additional warnings on the label, such as the boxed warning for PEMGARDA for anaphylaxis; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or other requirements subject to a REMS; • we may be required to change the way a product is administered or conduct additional trials; • we could be sued and held liable for harm caused to patients; • we may decide to remove the product from

the market; • we may not be able to achieve or maintain third- party payor coverage and adequate reimbursement; • we may be subject to fines, injunctions or civil or criminal penalties; and • our reputation and physician or patient acceptance of our products may suffer. There can be no assurance that we will resolve any issues related to any product- related adverse events to the satisfaction of the FDA or foreign regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if authorized or approved, and could significantly harm our business, results of operations and prospects. Lack of awareness or negative public opinion of mAb therapies and increased regulatory scrutiny of mAb therapies to prevent or treat COVID- 19 may adversely impact the development or commercial success of our product candidates. The clinical and commercial success of our mAb therapies for COVID- 19 will depend in part on public acceptance of the use of mAb therapies to prevent or treat COVID- 19. Any adverse public attitudes about the use of mAb therapies may adversely impact our ability to enroll clinical trials or successfully commercialize any of our mAb therapies that are authorized or approved. Moreover, our success will depend upon physicians prescribing, and their patients' willingness to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. **Additionally, our success may be impacted by overall evolving dynamics in the commercial market for COVID- 19 therapeutics, such as greater seasonality of demand, particularly as COVID- 19 has developed into an endemic disease.** More restrictive government regulations or negative public opinion may have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products that are authorized or approved. Adverse events in our or others' clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the ~~testing or~~ authorization or approval of our product candidates, stricter labeling requirements for those product candidates that are authorized or approved ~~and~~ **or** a decrease in demand for any such product candidates, all of which would have a negative impact on our business and operations. We may experience delays or difficulties in the enrollment and / or retention of patients in clinical trials, or we may pause, delay or terminate enrollment of our clinical trials, which could in turn delay or prevent our receipt of necessary regulatory **authorizations or** approvals. Successful and timely completion of clinical trials will require that we enroll, and maintain the enrollment of, a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors that may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates. Further, we may determine that enrollment in a clinical trial should be paused, delayed or terminated in order to revise trial protocols in light of preliminary data generated by the trial or new data generated in other studies. For example, following our review of data generated in external in vitro analyses examining the neutralizing activity of adintrevimab against the Omicron SARS- CoV- 2 BA. 1 variant in both authentic and pseudovirus assays, in January 2022 we paused enrollment of new patients in both our EVADE (evaluating adintrevimab for the prevention of COVID- 19) and STAMP (evaluating adintrevimab for the treatment of COVID- 19) clinical trials to assess dosing strategy and revise our trial protocols in light of the global spread of the Omicron variant and its sublineages; we reported preliminary safety and efficacy data from both trials in March 2022, but as a result of the lack of neutralizing activity against the Omicron BA. 2 variant, we paused the submission of an EUA request, and we have closed such trials. Trials may also be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. 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 patients to participate in these trials as required by the FDA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling patients in future clinical trials. Patient enrollment is affected by other factors, including: • the ~~contraction of the public health crisis caused by COVID- 19; • the~~ eligibility and exclusion criteria for the trial in question; • the size of the patient population and process for identifying patients; • the severity and difficulty of diagnosing the disease under investigation; • the impact infection prevalence may have on enrollment, as well as the emergence and evolution of SARS- CoV- 2 variants, which may impact the prevalent variant of infection for patients at one or more clinical trial sites and adversely impact enrollment potential; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • the design of the trial protocol, including but not limited to the use of a placebo control or active comparator; • the perceived risks and benefits of the product candidate in the trial, including relating to mAb and / or vaccine approaches; • the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation; • the willingness of patients to be enrolled in our clinical trials; • the ability to obtain and maintain subject consents ~~; • local, national and / or employer COVID- 19 vaccine mandates~~ ; • the efforts to facilitate timely enrollment in clinical trials; • potential disruptions caused by a public health crisis, such as the COVID- 19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, vaccine mandate policies, travel or quarantine policies that may be implemented, our ability to import and export clinical trial supplies, raw materials and commercial supply and other factors; • the patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • the risk that subjects enrolled in our clinical trials will drop out of the trials before completion; and • the proximity and availability of clinical trial sites for prospective patients. Our inability to enroll, or maintain the enrollment of, a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment pauses or delays in clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we will have limited influence over their performance. **The accelerated approval pathway, a fast track designation or a** ~~Breakthrough~~ **breakthrough** therapy

designation in the U. S. or the equivalent thereof in foreign jurisdictions (where available) for any product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive **full** marketing approval. **The FDA has established various expedited drug development programs to facilitate more rapid and efficient development, review and approval of certain types of drugs. Such programs include accelerated approval, fast track designation and breakthrough therapy designation. The FDA has broad discretion on whether or not to admit a drug candidate for these programs, so even if we believe a particular product candidate is eligible for an expedited drug development program, we cannot be sure that the FDA would agree. Even if any of our product candidates is admitted to any of the expedited drug development programs, we may not experience a faster development process, review or approval compared to conventional FDA timelines, and the FDA may still ultimately decide to not grant full marketing approval to such product candidates. For example, we may, in the future, pursue accelerated approval, if we pursue a BLA, or the equivalent thereof in foreign jurisdictions (where available), for our product candidates. The FDA may grant accelerated approval to a product candidate for a serious or life- threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product candidate has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of a grant of accelerated approval, the FDA may require that the sponsor perform one or more controlled post- marketing clinical trials. Accelerated approval of a product candidate may be withdrawn if these trials fails to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the product candidate (e. g., shows a significantly smaller magnitude or duration of benefit than was anticipated based on the observed effect on the surrogate).** We **may, in the future, pursue fast track designation in the U. S., or the equivalent thereof in foreign jurisdictions (where available), which is designed to facilitate the development and expedite the review of therapies for serious conditions that fill an unmet medical need. A product candidate with a fast track designation may benefit from early and frequent communications with the FDA, be eligible for priority review and has the ability to submit a rolling application for regulatory review. If any of our product candidates receive fast track designation but do not continue to meet the criteria for fast track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply or due to other issues, we will not receive the benefits associated with the fast track program. Fast track designation alone does not guarantee qualification for the FDA' s priority review procedures. In addition, we** may, in the future, apply for breakthrough therapy designation in the U. S., if we pursue a BLA, or the equivalent thereof in foreign jurisdictions (where available), for our product candidates. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. 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~~. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA. **Granting accelerated approval, fast track** ~~Designation~~ **designation or** ~~as a~~ breakthrough therapy **designation** is within the discretion of the FDA. Accordingly, even if we determine to pursue a BLA and we believe that one of our product candidates meets the criteria for **accelerated approval, fast track** designation **or** ~~as a~~ breakthrough therapy **designation**, the FDA may disagree and instead determine not to ~~make~~ **grant** such designation. ~~In any event~~ **Even if one or more of our product candidates receives conditional approval via the accelerated approval pathway, the FDA may later decide that the product candidate no longer meets the qualifying criteria for such approval, or it may decide that the confirmatory trial (s) failed to verify the clinical benefit or demonstrate sufficient clinical benefit to justify the risks associated with the product candidate, and the FDA may withdraw its conditional approval and / or refuse to grant full approval. Furthermore**, the receipt of a **fast track designation or** breakthrough therapy designation for a product candidate may not result in a faster development process, review or **full** approval compared to product candidates considered for approval under conventional FDA procedures **or the traditional FDA approval pathway**, and ~~it~~ **such designations** would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify ~~as~~ **for fast track designation or** breakthrough ~~therapies~~ **therapy designation**, the FDA may later decide that the product candidate no longer meets the conditions for qualification, or it may ~~decide that~~ **otherwise not shorten** the ~~time~~ **application review** period ~~for FDA review or approval will not be shortened~~. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific indications. As such, our current mission is focused on antibody- based therapies that protect vulnerable people from the consequences of viral threats, beginning with SARS- CoV- 2, and we have committed a significant portion of our financial and personnel resources to the manufacturing and commercialization of PEMGARDA, which received an EUA from the FDA in March 2024 **, and the development of VYD2311, our next generation mAb candidate for COVID- 19**. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could change, dissipate or stabilize, which could limit or eliminate demand for PEMGARDA **, VYD2311** or any new ~~or engineered~~ mAb candidates that we anticipate

periodically introducing in the future as the SARS- CoV- 2 virus evolves over time. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We have conducted and may in the future conduct clinical trials for our product candidates outside the U. S., and the FDA and similar foreign regulatory authorities may not accept data from such trials conducted in locations outside of their jurisdiction. We have conducted and may in the future conduct clinical trials for our product candidates outside the U. S. The FDA may not accept or may impose additional conditions on trial data from clinical trials conducted outside the U. S. submitted in support of an IND, EUA or BLA. For example, in order for the FDA to accept a foreign clinical trial as support for an IND or application for marketing approval, the FDA requires the following conditions are met: (i) the foreign data are applicable to the U. S. population and U. S. medical practice; (ii) the trial was conducted in accordance with cGCP standards; and (iii) the FDA is able to validate the data from the trial through an onsite inspection if the FDA deems it necessary. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the U. S. or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or authorization for commercialization in the applicable jurisdiction. We may not be successful in our efforts to build a pipeline of additional product candidates through internal efforts or through partnerships for discovery of novel antibody product candidates. We may not be able to continue to identify and develop new product candidates in addition to our current pipeline. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be successfully developed, much less receive authorization or approval and achieve market acceptance. Further, even if we obtain authorization or approval for a product candidate for one indication that may have potential for new or additional indications, we may determine that those additional indications are not worth pursuing for strategic reasons, including new legislation that may impact our ability to commercialize such compounds for such indications, if **authorized or** approved. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which ~~likely~~ would result in significant harm to our financial position and adversely affect our stock price. Our business and operations may be adversely affected by public health outbreaks, pandemics or epidemics, such as the COVID- 19 pandemic. COVID- 19, the disease caused by SARS- CoV- 2 and its variants, gave rise to a global pandemic in 2020, and continues to present public health and economic challenges around the world ~~. The full impact of the COVID- 19 pandemic remains uncertain, and such impact may directly or indirectly affect the commercial prospects of our product candidates for the prevention and treatment of COVID- 19~~ . The evolution and of the disease and the continued emergence of VoCs, and the availability, administration and acceptance of vaccines, mAbs, antiviral agents and other therapies may affect the design and enrollment of our clinical trials, the potential regulatory authorization or approval of our product candidates and the commercialization of our product candidates, if authorized or approved. In addition, our business and operations may be more broadly adversely affected by public health outbreaks, pandemics or epidemics, such as the COVID- 19 pandemic, which pose the risk that we or our third- party contractors may be prevented from conducting normal business activities or operations due to spread of the disease, or due to restrictions that may be requested or mandated by federal, state or local governmental authorities. ~~Business disruptions could include travel restrictions, temporary closures of our facilities or the facilities of our third- party contractors or other restrictions by authorities to reduce the spread of the disease. Any such business disruptions may negatively impact productivity, raise the cost of materials or otherwise disrupt our supply chain or manufacturing activities, and may disrupt our ongoing research and development activities as well as our clinical programs and timelines or commercialization efforts, the magnitude of which will depend, in part, on the length and severity of any such business disruptions, restrictions or other limitations on our ability to conduct our business in the ordinary course.~~ We experienced some delays in our development activities as a result of the COVID- 19 pandemic. For example, in December 2020, shipment of adintrevimab clinical supply by WuXi Biologics was delayed due to the introduction by the Chinese government of a new procedure for the approval of the export of products for the treatment of COVID- 19. There could be other disruptions, delays or uncertainties in our development activities as a result of any **future** public health outbreak, pandemic or epidemic ~~, such as the COVID- 19 pandemic~~ . Public health outbreaks, pandemics or epidemics, such as the COVID- 19 pandemic, which caused a broad impact globally, may also materially affect us economically. For example, a widespread outbreak, pandemic or epidemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity ~~. In addition, a recession or market correction resulting from the spread of disease such as COVID- 19 could materially affect our business and the value of our common stock. The ultimate extent to which COVID- 19 directly or indirectly impacts our business, financial condition, operations, and product development timelines and plans remains uncertain and will depend on future developments, including the duration and spread of outbreaks and the continued emergence of VoCs, actions taken to prevent or treat COVID- 19, and its economic impact on local, regional, national and international markets~~ . In addition, to the extent that any public health outbreaks, pandemics or epidemics, such as the COVID- 19 pandemic, adversely affects our business, financial condition and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this " Risk Factors " section. **Our** ~~We may develop~~ product

candidates ~~for use in combination with other therapies or third- party product candidates, which exposes us to additional regulatory risks. We may develop product candidates for use in combination with one or more currently authorized or approved therapies to prevent or treat COVID- 19, or with therapies that may be authorized or approved in the future. Even if any product candidate we develop were to receive authorization or approval to be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA or comparable foreign regulatory authorities could revoke authorization or approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. We may also evaluate our product candidates in combination with one or more other third- party product candidates that have not yet been authorized or approved by the FDA or comparable foreign regulatory authorities. If so, we will not be able to market and sell any product candidate we develop in combination with any such unauthorized or unapproved therapies that do not ultimately obtain authorization or approval. If the FDA or comparable foreign regulatory authorities do not authorize or approve these other product candidates, or revoke their authorization or approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biologics or antivirals we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain authorization or approval of or market any such product candidate. Even if our product candidates obtain regulatory authorization or approval, they~~ may be negatively impacted by future development or regulatory difficulties. Authorized and approved drug products are subject to ongoing regulatory requirements and oversight, including requirements related to manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting. In addition, we **are** ~~will be~~ subject to continued compliance with cGMP and cGCP requirements for any clinical trials that we conduct post- authorization or approval. If we or any of the third parties on which we rely fail to meet those requirements, the FDA or comparable regulatory authorities outside the U. S. could initiate enforcement action. Other potential consequences include the issuance of fines, warning letters, untitled letters or holds on clinical trials, product seizure or detention or refusal to permit the import or export of our product candidates, permanent injunctions and consent decrees, or the imposition of civil or criminal penalties, any of which could significantly impair our ability to successfully commercialize a given product. If the FDA or a comparable regulatory authority outside the U. S. becomes aware of new safety information, it can impose additional restrictions on how the product is marketed or may seek to withdraw marketing authorization or approval altogether. The United Kingdom' s withdrawal from the European Union may adversely impact our ability to obtain regulatory authorizations or approvals of our product candidates in the European Union and United Kingdom, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union and United Kingdom and require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union and United Kingdom. Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to by the United Kingdom and the European Union, as of January 1, 2021, the United Kingdom is no longer subject to the transition period (the " Transition Period ") during which European Union rules continued to apply. A trade and cooperation agreement (the " Trade Cooperation Agreement ") that outlines the post- Transition Period trading relationship between the United Kingdom and the European Union was agreed to in December 2020 and was formally entered into on May 1, 2021. Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from European Union directives and regulations, Brexit has had, and will continue to have, a material impact on the regulatory regime with respect to the potential development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom. For example, Great Britain (England, Scotland and Wales) is no longer covered by the centralized procedures for obtaining European Union- wide marketing authorizations from the European Commission, and a separate marketing authorization is required to market our product candidates in Great Britain. Northern Ireland continues to be covered by the marketing authorizations granted by the European Commission, but this ~~will change~~ **changed** ~~beginning~~ on January 1, 2025, when the new measures under the Windsor Framework ~~come~~ **came** into effect. Beginning on this date, Northern Ireland **is** ~~will be~~ subject to the same MHRA authorization procedures as Great Britain. All of these changes could increase our costs and otherwise adversely affect our business to the extent that we pursue development, manufacture, and / or commercialization of our product candidates in the European Union or United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would delay or prevent us from commercializing our product candidates in the United Kingdom. The Annex to the Trade and Cooperation Agreement further provides a framework for the recognition of cGMP inspections and for the exchange and acceptance of official cGMP documents. The regime does not, however, extend to procedures such as batch release certification. Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is treated as a " third country, " a country that is not a member of the European Union and whose citizens do not enjoy the European Union right to free movement. Northern Ireland continues to follow many aspects of the European Union regulatory rules, particularly in relation to trade in goods. As part of the Trade and Cooperation Agreement, the European Union and the United Kingdom recognize cGMP inspections carried out by the other party and the acceptance of official cGMP documents issued by the other party. The Trade and Cooperation Agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The United Kingdom has unilaterally agreed to accept European Union batch testing and batch release, and any change to this position is subject to a minimum two year notice period. However, the European Union continues to apply European Union laws that require batch testing and batch release to take place in the European Union territory. This means that medicinal products that are tested and released in the United Kingdom must be retested and re- released when entering the European Union market for commercial use. While the Trade and Cooperation Agreement provides for the tariff- free trade of medicinal products between the United Kingdom and the

European Union, there are additional non- tariff costs to such trade that did not exist prior to the end of the post- Brexit Transition Period. Further, should the United Kingdom diverge from the European Union from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore face significant additional expenses (when compared to prior to the end of the Transition Period) to operate our business, to the extent that we pursue development, manufacture, and / or commercialization of our product candidates in the European Union and United Kingdom, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import / export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non- tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom. Risks Related to the Manufacturing of our Product Candidates Monoclonal antibody therapies are complex ~~and~~ **,** difficult **and time-consuming** to manufacture, and we currently rely on a **single** contract manufacturer ~~for access to capacity~~. We could experience manufacturing problems, may be unable to access desired **future** manufacturing capacity within desired timeframes, or may be unable to access raw materials due to global supply chain shortages or otherwise, that result in delays in the development or commercialization of our product candidates or otherwise harm our business. The manufacture of ~~mAb~~ **mAbs** and other protein- based therapies are technically complex and necessitate substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical trials or commercialization efforts. We have engaged WuXi Biologics, a CDMO, for the development and manufacture of our product candidates for clinical and commercial use. Manufacturers of pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal regulations, as well as foreign requirements when applicable. Any failure of us or our CDMO to adhere to or document compliance to such regulatory requirements could lead to a delay or interruption in the availability of product for clinical trials or commercial use, or enforcement action from the FDA or foreign or state regulatory authorities. If we or our CDMO were to fail to comply with the FDA or foreign or state regulatory authorities, it could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of authorizations or approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins, if any, and our ability to commercialize any product candidates that receive regulatory authorization or approval on a timely and competitive basis. Biological products are inherently difficult and time- consuming to manufacture. Our program materials are manufactured and tested using technically complex processes and / or methods requiring specialized equipment and facilities and other production constraints, including a number of highly specific raw materials, cell lines and reagents with limited suppliers. Even though we aim to have backup supplies of raw materials, cell lines and reagents whenever possible, we cannot be certain they will be sufficient if our primary sources are unavailable. A shortage of a critical raw material, cell line or reagent, or a technical issue during development, manufacturing or testing, may lead to an inability to manufacture our product candidate, resulting in delays in clinical development or commercialization plans. Any changes in the manufacturing of components of the raw materials we use for manufacturing or testing of our product candidates could result in unanticipated or unfavorable effects in our manufacturing processes or product quality or timelines, resulting in delays. ~~Any~~ **Given the complex, difficult and time-consuming nature of manufacturing our product candidates, we must devote significant resources to the manufacture of our product candidates for clinical and potential commercial supply prior to receiving regulatory authorization or approval, and we may not realize a return on our investment in such supply if a product candidate is not ultimately authorized or approved. For example, we built supply of adintrevimab in anticipation of seeking regulatory authorization, but based on feedback from the FDA regarding adintrevimab' s lack of neutralizing activity against the Omicron BA. 2 variant, we paused the submission of an EUA request. More recently, we have incurred substantial costs in building supply of VYD2311, which is currently in Phase 1 development, and we cannot be certain as to if or when we will receive regulatory authorization or approval for such product candidate. While we believe that we have secured sufficient supply to meet demand for PEMGARDA and anticipated initial demand for VYD2311, if authorized or approved, any** delay, failure or inability to manufacture or test on a timely basis ~~can~~ **in the future could** impact the timelines for our **future** clinical trials or our commercialization plans. Such delay, failure or inability to manufacture or test can result from: • a failure in the manufacturing process itself, for example by an error in manufacturing process, operator or human error, equipment failure, raw material or reagent failure, failure in any step of the manufacturing process, failure to maintain a cGMP environment or failure in quality systems applicable to manufacture (whether by us or our third- party contract development and manufacturing organization), sterility failures, testing failure or contamination during processing; • a lack of reliability or reproducibility in the manufacturing process itself leading to variability in process execution or in product quality, which may lead to regulatory authorities placing a hold on a clinical trial or commercial supply and distribution or requesting further information on the process, which could in turn result in delays to the clinical trials or commercial supply and distributions; • inability to obtain manufacturing or testing slots within desired timeframes or to have enough manufacturing slots to manufacture our product candidates to meet clinical or commercial requirements and demands; • unfavorable FDA or foreign or state regulatory inspection of the manufacturing or testing site; • inability to procure raw materials and reagents due to global supply chain shortages or otherwise; • loss, depletion or performance degradation of the cell line starting material; and • loss of or close- down of any manufacturing facility used in the manufacture of our product candidates, or the inability to find alternative manufacturing capability in a timely fashion. Our product candidates are biologics, and the manufacture of our product candidates is complex and subject to extensive regulations. If we or our third- party contractors fail to comply with such regulations, regulatory authorities may impose sanctions or require remedial measures that could be costly or time- consuming, and our ability to provide supply of our product candidates for clinical trials or commercialization could be delayed or stopped.

All entities involved in the preparation of therapeutics for clinical trials or commercialization, including our existing contract manufacturer and testing facilities, labeling, packaging and storage facilities, and distributors, are subject to extensive regulation. Components of a finished therapeutic product authorized or approved for commercialization or used in clinical trials must be manufactured, tested, and stored in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and ensure the quality of investigational products and products authorized or approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturer must supply all necessary documentation in support of regulatory authorization or approval on a timely basis. Our facilities and quality systems and the facilities and quality systems of some or all of our third- party contractors will likely need to pass a pre- approval inspection (and may need to pass a pre- authorization inspection) for compliance with the applicable regulations as a condition of regulatory approval (or authorization) of our product candidates. In addition, regulatory authorities may, at any time, audit or inspect us or any of our contract manufacturing, testing, and storage facilities involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted, and they could put a hold on one or more of our clinical trials (or could delay regulatory authorization or approval) if the facilities or quality systems of our or third- party contractors do not pass such audit or inspections. Certain of our third- party contractors' facilities have not yet been inspected by regulatory authorities. If any of our third- party contractors' facilities do not pass a pre- approval, pre- authorization, or other facility inspection, regulatory approval or authorization of the products may not be granted. The regulatory authorities also may, at any time following authorization or approval of a product for sale, inspect or audit us or our third- party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if compliance discrepancies with our product specifications or violations of applicable regulations occur independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and / or time- consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business. If we or any of our third- party contractors fail to maintain regulatory compliance, the FDA or other regulatory authorities can impose regulatory sanctions, including, among other things, refusal to authorize or approve a pending application or to issue a positive opinion for a new drug product, or revocation of a pre- existing authorization or approval. As a result, our business, financial condition and results of operations may be harmed. Additionally, if supply from an approved manufacturer is interrupted, there could be a significant disruption in commercial supply of any authorized or approved products. An alternative manufacturer would need to be qualified and approved, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired commercial timelines. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully, if authorized or approved, or could delay commercial supply once authorized or approved. Furthermore, if our third- party contractors fail to meet contractual requirements, and we are unable to secure one or more replacement contractors capable of production at a substantially equivalent cost, our clinical trials or commercialization efforts may be delayed or we could lose potential revenue. We currently depend on sole- source third- party suppliers and a single contract manufacturer for materials and services that are necessary for the conduct of preclinical studies, manufacture and testing of our product candidates for clinical trials and **commercial supply** ~~the commercialization of PEMGARDA~~ , and the loss of these third- party suppliers or contract manufacturer or their inability to supply us with sufficient quantities of adequate materials or services, or to do so at acceptable quality levels **, acceptable pricing terms,** and on a timely basis, could harm our business. Manufacturing and testing our product candidates and commercialization of ~~PEMGARDA or~~ any ~~other~~ authorized or approved products ~~require~~ **requires** many specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture and testing of our product candidates. For example, we are reliant on WuXi Biologics, our current CDMO, as the procurer of the raw materials used in the manufacture of our product candidates ~~, such as PEMGARDA~~ , including certain single- source purification resins and cell culture media, which increases the risk of delays in production. Our current CDMO' s or potential future CDMOs' raw material suppliers may not have the capacity to support clinical and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill- equipped to support our needs. We also do not have supply contracts with many of these suppliers directly, and we, our current CDMO or potential future CDMOs may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we, our current CDMO or potential future CDMOs may experience delays in receiving key raw materials and equipment to support clinical or commercial manufacturing. For some of these specialty materials, we, our current CDMO or potential future CDMOs rely on and may in the future rely on sole- source suppliers or a limited number of suppliers. The supply of specialty materials and equipment that are necessary to produce our product candidates could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier could result in delay, and we may not be able to find other acceptable suppliers on acceptable terms, or at all. Switching our suppliers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If our key suppliers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, test, manufacture and market our product candidates in a timely and competitive manner, or at all. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes

or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business. In addition, to date, we have relied on WuXi Biologics as our only CDMO. We have partnered with WuXi Biologics for CMC development and for clinical and commercial drug substance and drug product supply. ~~The~~ **While we believe that we have secured sufficient supply to meet demand for PEMGARDA and anticipated initial demand for VYD2311, if authorized or approved, the** loss of this CDMO, a disruption in production at this CDMO or the inability of this CDMO to timely manufacture sufficient quantities **on acceptable pricing terms** to meet our needs, and our failure to find alternative manufacturing capability in a timely fashion, would impair our ability to develop and commercialize our product candidates ~~, including the manufacture and commercialization of PEMGARDA in quantities and on timelines sufficient to meet demand~~ . Although we believe there are other potential alternative CDMOs, the number of CDMOs with the necessary manufacturing and regulatory expertise and facilities to manufacture biologics like our mAb candidates is limited, and switching manufacturers or manufacturing sites would be expensive, difficult and time consuming. A new manufacturer or manufacturing site would have to be educated on, or develop substantially equivalent processes for, production of our product candidates, and it may be difficult or impossible to transfer certain elements of our manufacturing process to a new manufacturer or for us to find a replacement manufacturer on acceptable terms quickly, or at all. Furthermore, switching manufacturers or manufacturing sites may hinder our ability to leverage our ~~INVYMAB~~ platform approach to facilitate the ~~rapid, serial~~ generation of mAbs to keep pace with evolving viral threats, which we expect will require a consistent CMC platform. Transferring manufacturing to a new manufacturer or manufacturing site could therefore interrupt supply, delay our clinical trials and commercialization efforts, increase our costs for our product candidates and disrupt our plans to use any potential streamlined development pathway that requires a consistent CMC platform, any of which could have an adverse effect on our business, financial condition, results of operations, and / or growth prospects. Any contamination or interruption in our manufacturing process, shortages of raw materials or failure of our suppliers of reagents to deliver necessary components could result in delays in our clinical development or commercialization schedules. Given the nature of mAb manufacturing, there is a risk of contamination, including in the manufacture of raw materials and in the manufacturing of our product candidates, or in the manufacturing or testing facility itself. Any contamination could adversely affect our ability to supply product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture or testing of our product candidates could adversely impact or disrupt the supply of commercial or clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently or impact product stability and expiry and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes or could impact our planned development or commercialization schedule. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Risks Related to the Commercialization of Our Product Candidates If the FDA revokes or terminates our EUA for PEMGARDA, we will be required to stop commercial distribution of PEMGARDA immediately unless we can obtain FDA approval for PEMGARDA under a traditional regulatory pathway, which ~~is~~ **may be** lengthy and expensive, which could harm our future business prospects. Under the FDCA, the FDA has authority to allow certain unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life- threatening diseases or conditions when there are no adequate, approved, and available alternatives. In issuing an EUA, the FDA will consider the totality of scientific evidence available to the FDA regarding safety, efficacy, and known and potential risks of such products and availability of alternatives to the emergency use products, among others. EUAs issued by the FDA specify the scope of authorization and conditions of authorization, including limitations on distribution and conditions related to product advertising and promotion. Once granted, an EUA is effective until the declaration permitting emergency use authorization is terminated or the EUA is revoked, after which the product must be approved by the FDA under a traditional pathway in order to remain on the market or to continue commercialization of the product **in the U. S** . On March 22, 2024, we received an EUA from the FDA for PEMGARDA for the pre- exposure prophylaxis (prevention) of COVID- 19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate- to- severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID- 19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS- CoV- 2. The distribution and advertising conditions set forth in our EUA limit our market opportunities and restrict how we can commercialize PEMGARDA. For example, according to our EUA, among other requirements, all descriptive printed matter, advertising, and promotional materials relating to the emergency use of PEMGARDA under the EUA must be consistent with the authorized labeling and other terms set forth in the EUA and such materials must be tailored to the intended audience, not take the form of reminder advertisements or reminder labeling, and be accompanied by authorized labeling under certain circumstances. In addition, according to our EUA, printed matter, advertising, and promotional materials relating to the emergency use of PEMGARDA must provide accurate descriptions of safety results and efficacy results on a clinical endpoint

(s) or surrogate endpoint (s) from the clinical trial (s) summarized in the authorized labeling, including any limitations of the clinical trial data as described in the authorized labeling, and contain certain clear and conspicuous statements regarding the emergency use authorization. In addition, the PEMGARDA Fact Sheet for Healthcare Providers **(" HCPs ")** includes a boxed warning for anaphylaxis. If the FDA' s policies and guidance change unexpectedly and / or materially or if we misinterpret them, potential sales of PEMGARDA could be adversely impacted. In addition, the FDA would be required to revoke our existing or any future EUA if HHS determines that emergency use is no longer warranted. The FDA may also revoke our existing or any future EUA if new evidence becomes available that indicates that PEMGARDA is not as safe, effective, or reliable as the data provided in the EUA request. For example, the FDA may revise or revoke the EUA for PEMGARDA based on changes in circulating SARS- CoV- 2 variants and a reduction in neutralizing activity or effectiveness of PEMGARDA against such variants. **PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90 %.** We cannot predict how long our EUA will remain effective, and we may not receive advance notice from the FDA regarding revocation of our EUA. The termination or revocation of our existing EUA for PEMGARDA would cause us to cease our commercialization efforts until and if we have obtained approval from the FDA through another regulatory pathway and would adversely impact our business, financial condition and results of operations. Additionally, changes in FDA policies, guidance, and requirements for the submission of an EUA request may delay authorization of any additional emergency uses for PEMGARDA. Further, given the high volume of EUA requests received by the FDA ~~and other factors due to the COVID- 19 pandemic, including any disruptions in the FDA' s normal operations~~, the FDA' s review of an amended or additional EUA request may be significantly delayed. The FDA may not grant an EUA for additional emergency uses of PEMGARDA on a timely basis or at all, which could harm our future business prospects. ~~Even~~ **For example, in July 2024, we submitted a request to the FDA to expand the existing EUA for PEMGARDA to cover treatment of mild- to- moderate COVID- 19 in certain immunocompromised patients, which request was denied by the FDA in February 2025. While we have submitted a response requesting that the FDA reconsider our EUA amendment request for treatment, we cannot be certain** if **or when the FDA may do so, or the outcome of** any ~~of our~~ **further engagement with the FDA regarding such request. Our** product candidates ~~receive authorization or approval, such as PEMGARDA, they~~ may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success, due to the product profile, reimbursement dynamics or other reasons. If any of our product candidates receive authorization or approval, such as PEMGARDA, which received an EUA from the FDA in March 2024, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community, due to the product profile, reimbursement dynamics or other reasons. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if authorized or approved for sale, including PEMGARDA, will depend on a number of factors, including: • the efficacy, safety and potential advantages compared to alternative treatments, including oral, intramuscular (IM) and intravenous (IV) options; • our ability to offer our products for sale at competitive prices; • the convenience and ease of administration **, including** compared to **any** alternative treatments; • product labeling or product insert requirements of the FDA or other foreign regulatory authorities, including any limitations or warnings contained in a product' s approved labeling, including any boxed warning (such as the boxed warning for anaphylaxis for PEMGARDA) or REMS; • whether we are required by the FDA or other regulatory authorities to conduct additional clinical trials or to modify the design of our current trials to support the initial or continued authorization or approval of a product candidate; • the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments; • our ability to hire and retain a sales force in the U. S.; • the strength of marketing and distribution support; • the availability of third- party coverage and adequate reimbursement for any product candidates, once authorized or approved; • the prevalence and severity of any side effects, such as anaphylaxis for which PEMGARDA received a boxed warning; • any restrictions on the use of our products together with other medications or requirements that our products be used in combination with other products; and • the ability to be effective against emerging ~~variants as a monotherapy or combination therapy. Even though we have received an EUA for PEMGARDA, it may not gain broad market acceptance among physicians, healthcare payors and others in the medical community. The commercial success of PEMGARDA is dependent upon physicians, healthcare providers and patients adopting PEMGARDA, which will be informed, in part, by the cost, convenience, safety and efficacy of PEMGARDA. The efficacy of PEMGARDA could be negatively impacted by novel strains of~~ SARS- CoV- 2 ~~with genetic variations~~ --- **variants** ~~from viral mutation~~ **. The commercial success of our product candidates, if authorized or approved, is dependent upon market acceptance by physicians, HCPs and patients, which will be informed, in part, by cost, convenience, route of administration, safety and efficacy, including efficacy against emerging SARS- CoV- 2 variants** over time. If we are unable **to continue** to build and maintain sales, marketing and distribution capabilities for PEMGARDA or any other product candidate that may receive regulatory authorization or approval, we may not be successful in commercializing PEMGARDA or such other product candidates if and when they are authorized or approved. We **began commercializing PEMGARDA after we received an EUA from the FDA in March 2024. As a result, we have limited experience marketing our product candidates. Our financial condition and results of operations are and will continue to be highly dependent on the ability of our marketing function to adequately promote PEMGARDA for appropriate patients in a manner that complies with applicable laws and regulations. We** will need to **continue to** build and maintain a commercial infrastructure to support the ~~anticipated~~ marketing and distribution of ~~our product candidates, which we will need to achieve commercial success for~~ PEMGARDA and any other product ~~candidate~~ **candidates that may be authorized** ~~for~~ **or** ~~which we may obtain authorization or marketing approval~~ **approved in the future** . To support the commercialization of PEMGARDA, we ~~have~~ **initially** directly hired key leaders for our sales, marketing, market access, and medical affairs teams, and **leveraged** ~~we are leveraging~~ contract organizations for certain field- based roles.

**We subsequently determined to invest in direct hire resources, including an internal sales force.** There are risks involved with **both** establishing our ~~commercial infrastructure. For example, the establishment of our~~ own ~~commercial team and / or the hiring and training of a contract sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we develop a commercial team and / or hire a contract sales force to establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to develop and maintain our~~ commercialization capabilities **and with entering into arrangements with** ~~include: • our inability or the inability of a~~ contract ~~organization to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once authorized or approved; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating independent sales, marketing and market access~~ organizations. To the extent that we rely on third parties to perform sales, marketing or distribution services ~~, such as our leveraging of contract organizations for certain field- based roles for the commercialization of PEMGARDA, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition~~ , we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. **On the other hand, there are risks involved with establishing our commercial infrastructure. For example, establishing and training our own commercial team is expensive and time consuming. Factors that may inhibit our efforts to continue to build and maintain our commercialization capabilities include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once authorized or approved; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating independent sales, marketing and market access organizations.** If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. ~~We began commercializing PEMGARDA after we received an EUA from the FDA in March 2024. As a result, we have only limited experience marketing our product candidates. Our financial condition and results of operations are and will continue to be highly dependent on the ability of our marketing function to adequately promote PEMGARDA for appropriate patients in a manner that complies with applicable laws and regulations.~~ A key element of our business strategy is the continued expansion of our marketing infrastructure and building brand awareness. As we **continue to** increase our marketing efforts in connection with the expansion of PEMGARDA sales, we will need to further expand the reach of our marketing networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate a skilled marketing workforce, directly or through contract organizations, with significant industry- specific knowledge in various areas, including healthcare, prophylactic treatments, complex biologics, and applicable laws and regulations. If we are unable to expand our marketing capabilities, we may not be able to effectively commercialize PEMGARDA. Relatedly, if any of our marketing platforms significantly increase their advertising fees, our ability to expand our marketing reach will be greatly impeded. Any such failure could adversely affect our reputation, revenue, and results of operations. The affected populations for our product candidates, including PEMGARDA, may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates. Our mission is to deliver antibody- based therapies that protect vulnerable people from the consequences of viral threats, beginning with COVID- 19. In considering the market potential for our product candidates, our projections of the number of immunocompromised people in the U. S. who may not adequately respond to COVID- 19 vaccination and the estimated U. S. total addressable market for our mAb candidates for the pre- exposure prophylaxis of COVID- 19 are estimates based on Invivyd- sponsored market research and our internal analysis. The number of immunocompromised people in the U. S. who may not adequately respond to COVID- 19 vaccination and the estimated U. S. total addressable market for our mAb candidates for the pre- exposure prophylaxis of COVID- 19 may turn out to be lower than expected, and patients may not be amenable to our product candidates or may become increasingly difficult to identify and access, all of which would adversely affect our financial condition, results of operations and prospects. Further, even if we obtain authorization or approval for our product candidates, the FDA or other regulators may limit their authorized or approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of our product candidates. A decline, or a widespread perception of a decline, in the spread or severity of COVID- 19, including disease due to variants with relative or absolute resistance to other products, or an increase in available alternative therapies for or widespread immunity to COVID- 19, could reduce the total addressable market for our product candidates targeting COVID- 19. Similarly, if new SARS- CoV- 2 variants are less impacted by our product candidates and their mechanism of action than expected and such variants become more prevalent, the number of patients that we will be able to successfully treat with our product candidates, if authorized or approved, such as PEMGARDA, will be decreased. The total addressable market opportunity for our product candidates, including PEMGARDA, will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included on the final label, if authorized or approved for sale in specified indications, acceptance by the medical community, patient access, and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward- looking and speculative. The process we have used in developing an estimated total addressable market has involved using a third party to model the number of people at high risk for severe COVID- 19 based on a combination of different data sets, such as the incidence and prevalence of different medical conditions based on primary literature, the portion of patients who are receiving immunosuppressants based on claims data, and interviews / surveys with health care professionals.

Accordingly, these estimates included in this filing may turn out to be inaccurate. Further, the data and statistical information used in this Annual Report on Form 10- K, and in our other filings with the SEC, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources. Any revenue we are able to generate from product sales will be dependent, in part, upon the size of the market in the U. S. (and any other jurisdiction for which we may in the future obtain an EUA or similar authorization or obtain regulatory approval and have commercial rights) and our ability to meet the market demand. If the markets or patient subsets that we are targeting are not as significant as we estimate, or if we do not have sufficient supply to meet the market demand, we may not generate significant revenues from sales of such products, even if authorized or approved. **Our commercial prospects may be harmed if academic or other third- party labs not related to us generate virologic activity data that creates doubt regarding the neutralization activity of pemivibart or any other of our product candidates, even if such data is ultimately shown to be inconsistent with neutralization data generated through our industrial- grade virology efforts. From time to time, academic or other third- party labs not related to us may produce and run tests on their own molecules meant to resemble our molecules, such as pemivibart, or may run tests on our molecules utilizing differing assays and put neutralization findings of unknown quality into the public domain. In connection with the EUA for PEMGARDA, the FDA has acknowledged that neutralization findings from sources other than our independent, contracted vendor may differ due to, among other reasons, assay differences or because the molecule tested by other labs differs from pemivibart in sequence. Nevertheless, publicly available neutralization data against emerging SARS- CoV- 2 variants are reviewed by the FDA and may be factored into the totality of evidence when considering the potential for adequate neutralization activity of PEMGARDA to support continued emergency use authorization. To the extent that virologic activity data in the public domain generated by academic or other third- party labs not related to us creates doubt regarding the neutralization activity of pemivibart or our other product candidates, it could adversely impact our regulatory authorization and market acceptance by HCPs or patients, particularly if such publicly available neutralization findings are referenced by the FDA in relation to the regulatory authorization of any product candidate of ours, which would adversely affect our commercial prospects and ability to generate revenues, even if such data is preliminary, non- peer- reviewed, and / or generated with molecules that are not authentic Invivyd molecules, and even if such data is ultimately shown to be inconsistent with neutralization data generated through our industrial- grade virology efforts. For example, in October 2024, we withdrew formal revenue guidance for FY2024 following growth headwinds after the FDA updated the PEMGARDA Fact Sheet for HCPs in August 2024 to include a link to contested, non- peer- reviewed neutralization data of a non- pemivibart antibody generated by an academic lab, which indicated that PEMGARDA may have reduced susceptibility to certain SARS- CoV- 2 variants, including KP. 3. 1. 1. In September 2024, we announced that pseudovirus in vitro neutralization data generated by our independent, contracted vendor as part of our industrial- grade virology efforts showed continued neutralizing activity of PEMGARDA against KP. 3. 1. 1 and other SARS- CoV- 2 variants tested, and later that month, the FDA re- issued an updated PEMGARDA Fact Sheet for HCPs to provide accurate in vitro neutralization activity of PEMGARDA against dominant circulating variants, including KP. 3. 1. 1. However, this series of events resulted in confusion in the HCP and vulnerable population communities with respect to PEMGARDA and negatively impacted our net product revenue growth. If academic or other third- party labs not related to us generate virologic activity data that creates doubt regarding the neutralization activity of pemivibart or any other of our product candidates, our regulatory authorization and our commercial prospects may be harmed, even if such data is ultimately shown to be inconsistent with neutralization data generated through our industrial- grade virology efforts.** Off- label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and / or subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product. If our product candidates are authorized or approved by the FDA or comparable foreign regulatory authorities, we may only promote or market our products for their specifically **authorized or** approved indications. We ~~will~~ train our marketing and sales force against promoting our products for uses outside of the **authorized or** approved indications ~~for use~~, known as " off- label uses. " We cannot, however, prevent a physician from using our products off- label. Furthermore, the use of our products for indications other than those authorized or approved by the FDA or comparable foreign regulatory authorities, may not effectively treat such conditions. Any such off- label use of our products could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for uses for which they are not authorized or approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation. Advertising and promotion of any product candidate that obtains authorization or approval in the U. S. will be heavily scrutinized by the FDA, the FTC, the Department of Justice (the " DOJ "), the Office of Inspector General of HHS, state attorneys general, members of the U. S. Congress, and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U. S. will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off- label uses, are subject to enforcement letters, inquiries, investigations, and civil and criminal sanctions by the FDA, DOJ or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to correct information to healthcare practitioners, injunctions, or civil or criminal penalties. The advertising and promotion of products in the European Union is subject to European Union Member States' national laws implementing Titles VIII and VIIIa of Directive 2001 / 83 / EC on the Community code relating to medicinal products for human use, Directive 2006 / 114 / EC concerning misleading and comparative advertising, and Directive 2005 / 29 / EC on unfair commercial practices, as well as other national legislation of individual European Union Member State governing the advertising and promotion of medicinal products. European Union Member States' legislation may also restrict or impose limitations on the ability to advertise products

directly to the general public. In addition, voluntary European Union and national Codes of Conduct provide guidelines on the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals. Any actual or alleged failure to comply with promotion requirements may result in fines, warning letters, injunctions, or civil or criminal penalties. Our mAb product candidates **, including PEMGARDA,** may face significant competition from vaccines, antiviral agents and other therapeutics, including mAbs, for COVID- 19 that are currently available or in development. Many biotechnology and pharmaceutical companies are developing therapeutics for COVID- 19 or vaccines against SARS- CoV- 2, the virus that causes COVID- 19. Many of these companies, which include large pharmaceutical companies, have greater resources for development and established commercialization capabilities. For example, the FDA has approved or granted EUA for several vaccines and therapeutics for the prevention or treatment of COVID- 19 developed or marketed by other companies, many of which are large, established biotechnology and pharmaceutical companies. Many of these companies have also been successful in securing government funding to support research and development and / or manufacturing of their product candidates as well as government contracts to purchase their supply orders. Additional vaccines and therapeutics are in development by other pharmaceutical and biopharmaceutical companies. Given the products currently approved or authorized for use as well as those in development by others, any therapies we may develop could face significant competition. If any other company develops therapeutics more rapidly or effectively than we do, develops a therapeutic that becomes the standard of care, develops a therapeutic with a perceived superior risk- benefit profile or other perceived superior attributes such as mode of administration or dosing regimen, develops a therapeutic at a lower cost or is more successful at commercializing an approved therapeutic, we may not be able to successfully commercialize ~~PEMGARDA or~~ **our** ~~any other~~ product ~~candidate~~ **candidates** targeting COVID- 19, even if authorized or approved, or compete with other therapeutics or vaccines, which could adversely impact our business and operations. For example, PEMGARDA has been authorized with a boxed warning for anaphylaxis, which could impede our ability to successfully market and commercialize PEMGARDA and our ability to compete successfully against our competitors. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery, development and manufacture of product candidates, as well as in obtaining regulatory authorizations or approvals of those product candidates in the U. S. and in foreign countries. Our current and potential future competitors may also have significantly more experience commercializing drugs, particularly mAbs and other biological products, that have been authorized or approved for marketing. Furthermore, a number of our competitors have received government contracts to support research and development of their product candidates and supply orders. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of **our competitors. Our success is also subject to the risk of current and future disruptive technologies, such as AI; if our competitors are able to more effectively utilize any such new technologies, including but not limited to those that may involve AI or be created using AI, to discover, develop and commercialize products that compete with any of our product candidates, such technologies could adversely impact our ability to compete against** our competitors. We will face competition from other drugs or from other non- drug products currently authorized, approved or that will be authorized or approved in the future for the prevention or treatment of diseases we intend to target. Therefore, our ability to compete successfully will depend largely on our ability to: • develop and commercialize drugs that are differentiated from products in the market; • demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies; • attract qualified scientific, product development and commercial personnel; • obtain patent or other proprietary protection for our medicines; • obtain and maintain required regulatory authorizations or approvals; • obtain placement in COVID- 19 prevention and treatment guidelines from organizations such as the CDC, the WHO and the Infectious Diseases Society of America (the " IDSA "); • obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third- party payors; • manufacture sufficient supply to meet market demand; and • successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines. The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop, including PEMGARDA. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects. In addition, the reimbursement structure of authorized or approved mAbs by other companies could impact the anticipated reimbursement structure of our mAbs, if authorized or approved, and our business, financial condition, results of operations and prospects. Additionally, government entities, such as the CDC, the WHO and non- government professional societies, such as the IDSA, may produce treatment and / or prevention guidelines for COVID- 19, including the use of mAbs for these indications. However, our mAbs, even if authorized or approved, may fail to be added to such guidelines or receive poor positioning within such guidelines, which may instead recommend products of our competitors. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an authorized or approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving authorization or approval for, or commercializing, drugs before we do, which would have an adverse impact on our business and results of operations. The success of **PEMGARDA and** our product candidates ~~will depend~~ **depends** significantly on coverage and adequate reimbursement or the willingness of patients to pay for these therapies. We believe our success depends on obtaining and maintaining coverage and adequate reimbursement for our product candidates, including PEMGARDA, and the extent to which patients will be willing to pay out- of- pocket for such products, in the absence of reimbursement for all or part of the cost. In the U. S. and in other countries, 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. The availability of coverage and adequacy of reimbursement for our products by third- party payors, including government

healthcare programs (e. g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor- by- payor basis **and may change from one calendar year to the next** . One payor' s determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement. In the U. S., the principal decisions about Medicare reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. CMS has published in the Calendar Year **2023** Physician Fee Schedule ~~a final~~ **Final** ~~rule~~ **Rule , and reaffirmed in subsequent Calendar Year Rulemaking, a policy** that all COVID- 19 mAbs for pre- exposure prophylaxis of COVID- 19 and their administration will be covered and reimbursed under the Part B preventative vaccine benefit. CMS has not communicated a timeline for publishing ~~this~~ **coverage** information **for** ~~following the granting of~~ any ~~EUAs by the FDA for~~ such ~~products~~ - **product once it has been granted an EUA** . A significant delay in publication of product specific billing codes and their **associated** payment rates could impact initial prescription rates by providers and **demand by** patients **. Furthermore, a delay by CMS in publishing updated payment limits following any price increase of a product could impact prescription rates by providers or lead to deferment in treatment for patients, which could adversely affect our sales** . Third- party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third- party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. In addition, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that a product is safe, effective and medically necessary; appropriate for the specific patient; cost- effective; supported by peer- reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. Government entities, such as the CDC, the WHO and non- government professional societies, such as the IDSA, may produce treatment and / or prevention guidelines for the prevention and treatment of COVID- 19, including guidance regarding the use of mAbs in these indications. If our product candidates, to the extent authorized or approved, fail to be added to these guidelines, or if they receive poor positioning within these guidelines, payors and other customers may be less inclined to add any such product candidate to their formularies, significantly reducing demand for such product candidate, if **authorized or** approved. Further, increasing efforts by third- party payors in the U. S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates, if **authorized or** approved. In order to secure coverage and reimbursement for any product that might be authorized or approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory authorizations or approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost- effective. If third- party payors do not consider a product to be cost- effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its product at a profit. We expect to experience pricing pressures from third- party payors in connection with the potential sale of any of our product candidates. Decreases in third- party reimbursement for any product or a decision by a third- party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales. Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system, to the extent any of our product candidates are authorized or approved outside of the U. S. For example, in many countries in the European Union, procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing authorization. Many European countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the European Union member states will continue to propose and implement cost- containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and / or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for products in some European countries, including some European Union member states, data comparing the cost- effectiveness of products to other available therapies may be required. Health Technology Assessment (" HTA ") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some European Union member states, including those representing the larger markets. The HTA process, which is currently governed by national laws in each European Union member state, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual European Union member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between European Union member states, although the HTA Regulation which aims to harmonize the clinical benefit assessment of HTA across the European Union **applies** ~~will apply~~ beginning on January 12, 2025. If in the future we seek but are unable to obtain and then maintain favorable pricing and reimbursement status in European Union member states that represent significant markets, our anticipated revenue from and growth prospects for products in the

European Union could be negatively affected. If we experience setbacks or unforeseen difficulties in obtaining favorable pricing and reimbursement decisions, any planned launches in the affected European Union member states would be delayed, which could negatively impact any anticipated revenue from and growth prospects for relevant product candidates. There can be no assurance that PEMGARDA or any other product candidate, if authorized or approved for sale in the U. S. or in other countries, will be considered medically reasonable and necessary, that it will be considered cost- effective by third- party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the U. S. and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are authorized or approved for sale. Any product candidates for which we determine to seek approval as biological products may face biosimilar competition sooner than anticipated. In the future, if we determine to pursue and we are successful in achieving regulatory approval to commercialize any biological product candidate that we develop, such approved product may face competition from biosimilar products. In the U. S., product candidates are regulated by the FDA as biological products subject to approval under the BLA pathway. The ACA includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological 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 by the FDA. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full 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 their 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. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for biological products. There is a risk that any of our product candidates approved as a biological product under a BLA, should we determine in the future to pursue such regulatory pathway, would not qualify for the 12- year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. ~~For example, in May 2021, the Biden administration expressed support for waiving intellectual property protections for COVID- 19 vaccines amid concerns about vaccine access in foreign nations. Such waiver, if implemented, could extend to our product candidates.~~ Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In the European Union, biosimilars can only be authorized once the period of data exclusivity on our candidate, as ' reference' biological medicinal product, has expired. In general, this means that the biological reference medicine must have been authorized for at least eight years before another company can apply for approval of a similar biological product. If competitors are able to obtain marketing approval for biosimilars referencing our candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and ~~will~~ face an even greater risk as we sell any products that have been authorized or approved, such as PEMGARDA, which received an EUA from the FDA in March 2024. Side effects or adverse events known or reported to be associated with, or manufacturing defects in, the products sold by us could exacerbate a patient' s condition, or could result in serious injury or impairment or even death. For example, in the CANOPY clinical trial, the most common adverse **reactions** ~~events (all grades, incidence ≥ 2 %) observed in participants who have moderate- to- severe immune compromise treated with PEMGARDA~~ included systemic ~~and local~~ infusion- related ~~or~~ **reactions and** hypersensitivity reactions, ~~upper respiratory tract infection~~ **local infusion site reactions** , ~~viral infection, influenza- like illness, fatigue, headache,~~ and ~~nausea~~ **infusion site infiltration or extravasation** . Anaphylaxis has been observed with PEMGARDA, and the PEMGARDA Fact Sheet for **HCPs** ~~Healthcare Providers~~ includes a boxed warning for anaphylaxis. This could result in product liability claims against us and / or recalls of one or more of our products. In many countries, including in European Union member states, national laws provide for strict (no- fault) liability which applies even where damages are caused both by a defect in a product and by the act or omission of a third party. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or drugs that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards paid to trial participants or patients; • loss of revenue; • exhaustion of any available insurance and our capital resources; • reduced resources of our management to pursue our business strategy; and • the inability to commercialize any products that we may develop. Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or ~~commence~~ **continue** commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our or our CDMO' s, CROs', contractors', consultants' or collaborators' cybersecurity. Maintaining the security of our information systems and communication systems is a critical issue for us, and we devote considerable internal and external resources to network security and other security measures to protect our systems and users,

but these security measures cannot provide absolute security. Moreover, even security measures that are deemed appropriate, reasonable, and / or in accordance with applicable legal **standards or** requirements may not be able to protect the information we maintain. The multitude and complexity of our information systems may furthermore make them susceptible to service interruption, ~~breaches of security~~ **cybersecurity incidents** , disruption of data integrity, inadvertent errors that expose our data or systems, malicious intrusion, or cyberattacks. Despite our efforts, the possibility of these events occurring, and the ever-changing threat landscape, cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber- attacks or ~~security~~ **cybersecurity** ~~breaches~~ **incidents** that could adversely affect our business. Our internal information systems, and those of third parties on which we rely, are also vulnerable to, among other things, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, system malfunctions, cyberattacks or cyber-intrusions over the Internet, ~~and~~ **social engineering (e. g.,** phishing attacks **), attacks enhanced or facilitated by AI, and other similar threats** . The source of these vulnerabilities may be persons inside or outside our organization. We have in the past and plan to in the future identify defects, errors, or vulnerabilities, which could inadvertently permit access to or exposure of data, including personal ~~information~~ **data** , that we maintain or which third parties maintain on our behalf. The risk of a cybersecurity incident, 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. For example, the ongoing conflict between Russia and Ukraine has led to an increase in cyberattacks on ~~the~~ Ukraine, including its government, companies, institutions and people, as well on the financial and communications infrastructure of other countries, companies and individuals therein. If any such event were to occur in countries in which we operate, it could lead to the loss, destruction, alteration, prevention of access to, disclosure, dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information and personal data) or data that is processed or maintained on our behalf, and cause interruptions in our operations, resulting in a material disruption of our product development programs. For example, the loss or alteration of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts ~~and~~ **,** significantly increase our costs to recover or reproduce the data **, and reduce trial participants' or patients' trust in us** . Additionally, such events could lead to an interruption in our supply chain for the manufacturing of clinical and commercial drug substance and drug product, as well as related materials, and could significantly impact development and commercialization timelines and capabilities. If our information systems or a third- party' s information systems on which we rely suffer severe damage, disruption or shutdown and issues are not resolved in a timely manner, we could experience delays in reporting our financial results, and we may lose revenue and profits as a result of our inability to timely manufacture or distribute our products. We continue to implement security measures to bolster our network security and protect our systems, however, such efforts are not guaranteed to prevent such events from occurring. We cannot ensure that our data protection efforts and our investment in information technology, or the efforts or investments of our CDMO, CROs, consultants or other third parties with which we work, will prevent cybersecurity incidents that cause loss, destruction, unavailability, alteration, dissemination of, or damage or unauthorized access to, our data, including personal data, assets and other data processed or maintained on our behalf, that could have a material adverse effect upon our reputation, business, operations or financial condition. We rely on third parties to manufacture, package and label our product candidates, and any data breaches or other ~~security~~ **cybersecurity** ~~events~~ **incidents** relating to their information systems, or the information systems of other business partners, could also have a material adverse effect on our business. Controls employed by our information technology department and our CDMO, CROs, consultants and other third parties could prove inadequate, and our ability to monitor such third parties' data security practices is limited. Due to applicable laws, rules, regulations and standards or contractual obligations, we may be held responsible for information security failures or cybersecurity incidents attributed to our third- party service providers as they relate to the information we share with them. Notifications and follow- up actions related to a data breach or other cybersecurity incident could impact our reputation and cause us to incur significant costs, including significant legal expenses and remediation costs as well as potential regulatory scrutiny. We expect to incur significant costs in an effort to detect and prevent cybersecurity incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived cybersecurity incident. However, we cannot guarantee that we will be able to detect or prevent any such cybersecurity incidents, or that we can remediate any such incidents in an effective or timely manner. Our efforts to improve security and protect data from compromise may also identify previously undiscovered cybersecurity incidents. To the extent that any disruption or cybersecurity incident was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information or personal data, we could incur material reputational harm, penalties, regulatory scrutiny, liabilities, legal claims, and / or mandated changes in our business practices, and the further development of our product candidates could be delayed. Any such event could also compel us to comply with federal and state breach notification laws, and foreign law equivalents, subject us to **investigations or** mandatory corrective action and otherwise subject us to substantial liability under laws, rules, regulations and standards that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. In addition, the cost and operational consequences of implementing further data protection measures could be significant, and theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Further, we cannot be certain that our liability insurance will be sufficient in type or amount to cover us against claims related to a cybersecurity incident, such coverage will cover any indemnification claims against us relating to any cybersecurity incident, such coverage will continue to be available to us on economically reasonable terms, or at all, or any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, could adversely affect our reputation,

business, financial condition and results of operations. We are subject to a variety of privacy and data security laws, rules, regulations, policies, industry standards and contractual obligations, and our failure to comply with them could harm our business. We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the U. S., there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the U. S., numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations, including Section 5 of the ~~Federal Trade Commission Act (“~~ FTC Act ~~”)~~ **and the FTC Health Breach Notification Rule** , that govern the collection, use, disclosure and protection of health- related and other personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act **, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder** (“ HIPAA ”) ~~, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder~~ . HIPAA imposes privacy and security obligations on **“ covered entities, ”** covered entity health care providers, health plans, and health care clearinghouses, as well as their “ business associates ” (i. e., certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function for or on behalf of a covered entity). Depending on the facts and circumstances, we could be subject to significant penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. At the federal level, the FTC also sets expectations for failing to take appropriate steps to keep consumers’ personal information secure, or failing to provide a level of security commensurate to promises made to individuals about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of the FTC Act. The FTC expects a company’ s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities ~~.~~ **, and has taken the position that** ~~Individually~~ **individually** identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations for failing to honor the privacy promises made to individuals about how ~~the~~ **a** company handles consumers’ personal information; such failure may also constitute unfair or deceptive acts or practices in violation of the FTC Act. **The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records.** Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. In Europe, the GDPR **, including as implemented in the UK,** governs the ~~collection, use, disclosure, transfer or other~~ processing of personal data of individuals within the European Economic Area (“ EEA ”) **and the UK** , including clinical trial data. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data breaches to the competent national data processing authorities, requires having lawful bases ~~on which~~ **for processing** personal data ~~can be processed and includes notice and~~ **(which may in certain situations require explicit** consent **of data** ~~requirements which may apply to clinical trial~~ subjects **)** ~~and investigators~~ . The GDPR imposes substantial fines for breaches and violations (for the most serious ~~breaches~~ **violations** of up to the greater of € 20 million or 4 % of annual global turnover) and confers the right for data subjects to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR ~~increases~~ **generally restricts** the ~~scrutiny of~~ transfers of personal data from the EEA, including the European Union, United Kingdom and Switzerland, to other jurisdictions that the European Commission / United Kingdom Secretary of State, as applicable, does not recognize as having “ adequate ” data protection laws **unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data** . While, previously, ~~United States~~ **U. S.** companies could rely on self- certification to the EU- U. S. and Swiss- U. S. Privacy Shield frameworks administered by the ~~United States~~ **U. S.** Department of Commerce as one of these safeguards to legitimize transfers from the European Union and Switzerland to the ~~United States~~ **U. S.** , this has been invalidated by the Court of Justice of the European Union (the “ CJEU ”). The CJEU found that the Standard Contractual Clauses (“ SCCs ”), one of the primary safeguards for legitimizing data transfers, were valid in principle, but placed obligations on the parties entering into them including to verify whether an adequate level of protection is provided in the recipient jurisdiction, and whether additional measures are required to bring the level of protection in line with European Union standards. Following this decision, the European Data Protection Board issued guidance on how organizations should approach international data transfers of GDPR- covered personal data, including the supplemental measures companies can adopt to help protect against overarching surveillance outside of the European Union. In June 2021, the European Commission adopted a new set of SCCs aimed at enabling lawful transfers of personal data to non- adequate countries outside the EEA, the deadline for the adoption of which was December 27, 2022. ~~There are also recent developments regarding data transfers in the United Kingdom, which formally approved two mechanisms for transferring United Kingdom- data overseas and that came into effect on March 21, 2022.~~ The United Kingdom Information Commissioner’ s Office also issued guidance on how to approach undertaking risk assessments for transfers of United Kingdom- data to non- adequate countries outside the United Kingdom. With respect to the ~~United States~~ **U. S.** , on July 10, 2023, the European Commission adopted its adequacy decision for the EU- US Data Privacy Framework, providing for personal data to flow freely from the European Union

to ~~United States~~ **U. S.** - based companies that participate in the Data Privacy Framework ~~. The adequacy decision followed the adoption by United States President Biden of an executive order as well as regulation issued by the United States Attorney General~~ . A lack of valid transfer mechanisms for GDPR- covered data could increase exposure to enforcement actions as described above and may affect our business operations and require commercial cost (including potentially limiting our ability to collaborate / work with certain third parties and / or requiring an increase in our data processing capabilities in the European Union and United Kingdom). Further, the European Union and United Kingdom data protection laws (including laws on data transfers as set out above) may also be updated / revised, accompanied by new guidance and / or judicial / regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time- intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Any failure or perceived failure by us, a company that we acquire, or one of our service providers to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data security could result in governmental investigations and enforcement actions, litigation, fines and penalties, exposure to indemnification obligations or other liabilities, and adverse publicity, all of which could have an adverse effect on our reputation, as well as our business, financial condition, and results of operations. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, the California Consumer Privacy Act ~~(" CCPA ") took effect on January 1~~ , ~~2020 and was~~ - **as** ~~later~~ amended by the ~~California Privacy Rights Act (" CPRA~~ - **CCPA** ~~"). The CPRA went into effect on January 1, 2023~~ . The CCPA ~~, as amended,~~ gives California ~~residents~~ **consumers (as defined by law)** expanded rights, including to access, correct and delete their personal information and to opt- out of certain personal information disclosures, including sales of their personal information ~~and use for cross- context behavioral advertising purposes~~ . It also requires covered companies to provide disclosures to California consumers and includes ~~new audit requirements for higher risk data and~~ opt- out rights for certain uses of sensitive data. ~~The~~ **Under the** ~~CPRA~~ - **CCPA , the** ~~also created a new~~ California data protection agency **is** authorized to issue substantive regulations **, including with respect to risk assessments and cybersecurity audits,** which could result in increased privacy and information security enforcement. The agency continues to draft and propose implementing regulations for the ~~CPRA~~ - **CCPA** . The ~~lack of certainty regarding the final state of these regulations could result in significant compliance costs. The amended~~ CCPA provides for civil penalties for violations, as well as a private right of action for data breaches of certain types of data that is expected to increase data breach litigation ~~. Although the CCPA currently exempts certain health- related information, including clinical trial data, the amended CCPA may increase our compliance costs and potential liability~~ . Similar state consumer protection laws have passed in other states **and there are now more than a dozen in effect** . ~~Such~~ **Future** laws **may** ~~, including those in Colorado, Connecticut, Utah and Virginia, went into effect during 2023 and~~ have potentially conflicting requirements that would make compliance challenging and present legal risk ~~. Other states, such as Indiana, Iowa, Montana,~~ and ~~Texas have implemented similar laws which~~ could result in significant compliance costs. **Health- specific consumer privacy laws were also passed in multiple states, including Washington and Nevada. Moreover, as a result of the broad scale release and availability of AI technologies such as generative AI, there is a global trend towards more regulation (e. g., the EU AI Act and AI laws passed in U. S. states) to ensure the ethical use, privacy, and security of AI and the data that it processes. Compliance with such laws will likely be an increasing and substantial cost in the future.** With the GDPR, CCPA and other ~~state~~ laws, regulations and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with the substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. However, these policies and practices may not be aligned with every applicable legal or regulatory standard immediately, due in part to the rapidly shifting landscape of privacy and data security requirements. A regulatory review or other independent assessment of the privacy program may result in identifying one or more areas of non- compliance. Additionally, if third parties with which we work, such as vendors or service providers, violate applicable laws, rules or regulations or our policies **or contractual obligations** , such violations may also put our or our clinical trial and employee data, including personal data, at risk, which could in turn have an adverse effect on our business. The landscape of laws regulating personal data is constantly evolving, and compliance with these laws requires a flexible privacy framework and substantial resources ~~, and~~ **. Accordingly** compliance efforts will likely be an increasing and substantial cost in the future. If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business. We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third- party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our

employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not 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 regulatory approvals could be suspended, which could seriously harm our business. Risks Related to Our Dependence on Third Parties We currently rely on third parties to conduct, supervise, analyze and monitor a significant portion of our **nonclinical activities** ~~research and preclinical testing~~ and clinical trials for our product candidates, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain **or maintain** regulatory **authorization or** approval or **successfully** commercialize product candidates, or such **authorization or** approval or commercialization may be delayed **or impaired** , and our business may be substantially harmed. We have engaged CROs and other third parties to conduct **nonclinical activities and** ~~our planned preclinical studies or~~ clinical trials **for our product candidates,** and to monitor and manage data. We expect to continue to rely on third parties ~~, including~~ **such as** clinical data management organizations, medical institutions and clinical investigators ~~,~~ to conduct ~~those clinical~~ **such activities and** trials. We also rely on third parties for their research and discovery capabilities **, including the nonclinical activity of assay development and virology testing of our product candidates** . Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties ~~or to do so~~ on commercially reasonable terms, if at all. Switching or adding CROs ~~involves substantial cost and~~ **or other third- party vendors** requires management time and focus ~~. In addition~~ , **and may involve substantial cost or** ~~there is a natural transition period when a new CRO commences work. As a~~ result ~~,~~ **in** delays **that** ~~occur, which can~~ materially impact our ability to meet our desired **program** ~~clinical development~~ timelines **for our product candidates** . Though we intend to carefully manage our relationships with our CROs **and other third- party vendors** , there can be no assurance that we will not encounter challenges or delays in the future or that ~~these~~ **any such** delays or challenges will not have a material adverse impact on our business, financial condition and prospects. In addition, any third parties conducting our **nonclinical activities or our** clinical trials **,** or monitoring and managing our data **,** 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 ~~clinical~~ programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, **or** if ~~they need to be replaced, or if~~ the quality or accuracy of the **nonclinical,** clinical **or other** data they **generate or otherwise** obtain is compromised or not **timely** made available to us or regulatory authorities, due to the failure to adhere to **applicable** ~~our clinical~~ protocols, regulatory requirements, contractual obligations or for other reasons, our **preclinical studies or** clinical trials may be extended, delayed or terminated, the strength **and reliability** of our ~~clinical~~ data ~~package~~ may be ~~limited~~ **adversely impacted** , **which** ~~and we~~ may ~~not be able~~ **impact our ability** to obtain **or maintain** regulatory **authorization or** approval **,** ~~for~~ **or result in modification to the regulatory authorization or approval documents (e. g., EUA fact sheet, letter of authorization or prescribing information), and may impact** ~~or~~ **our ability to** successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates ~~would~~ **may** be harmed, our costs could increase substantially and our ability to generate revenue could be ~~delayed~~ **impaired** significantly. ~~We rely on~~ **For example, following receipt of EUA from** ~~these~~ -- **the** ~~parties~~ **FDA in March 2024** for ~~execution~~ **PEMGARDA ™ (pemivibart) for the pre- exposure prophylaxis (prevention)** of ~~our preclinical studies~~ **COVID- 19 in certain adults** and ~~clinical trials,~~ **adolescent individuals (12 years of age** and ~~generally do not control~~ **older weighing at least 40 kg), we were informed in mid- July 2024 by our** ~~their~~ -- **third** ~~activities~~ **- party authentic virus neutralization assay (“ AVNA ”) vendor that a possible contamination event may have impacted the AVNA potency value generated by such vendor for pemivibart against JN. 1, which was the dominant circulating SARS- CoV- 2 variant in the U. S. between January 2024 and April 2024. Along with the pseudotyped viral neutralization assay (“ PVNA ”) potency value for pemivibart against JN. 1, the original PEMGARDA Fact Sheet for HCPs reflected the AVNA potency value for pemivibart against JN. 1. As a result of the possible contamination event at our third- party AVNA vendor that may have impacted the AVNA potency value for pemivibart against JN. 1, the FDA made modifications to the PEMGARDA Fact Sheet for HCPs, including, among other changes, removal of the AVNA potency value for pemivibart against JN. 1 and incorporation of certain other available information for HCPs to consider when determining whether to prescribe PEMGARDA** . Our reliance on ~~these~~ **CROs and other** third parties ~~for research and development activities will reduce~~ **reduces** our control over ~~these~~ **our nonclinical** activities **and clinical trials,** but ~~will~~ **does** not relieve us of our **regulatory** responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as **cGCPs** ~~good clinical practices~~ , for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA ~~, EMA~~ or comparable foreign regulatory authorities may require us to perform additional clinical trials before **authorizing or** approving our ~~marketing applications~~ **product candidates** . We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory **authorization or** approval process **for our product candidates** . We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government- sponsored database, such as ClinicalTrials. gov,

within specified timeframes. This remains our obligation regardless of whether we have contracted any third party to assist and failure to do so can result in fines, adverse publicity and civil and criminal sanctions. In addition, principal investigators for our 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. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA 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~~ **, which may lead to the** delay ~~in approval, or rejection, of our~~ **or** ~~marketing applications by the FDA and may ultimately lead to the~~ denial of ~~marketing~~ **regulatory authorization or** approval for our product candidates. We also expect to rely on other third parties to label, package, store and distribute product supplies for our clinical trials. Any performance failure on the part of ~~our distributors~~ **such third parties** could delay clinical development or marketing approval or authorization of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue. **If our CROs or other third- party vendors do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain or maintain regulatory authorization or approval or successfully commercialize product candidates, or such authorization or approval or commercialization may be delayed or impaired, and our business may be substantially harmed.** We ~~intend to~~ rely on third parties to manufacture, test, label, package, store and distribute clinical and commercial supplies of our product candidates. We ~~are~~ currently **rely on third parties for** manufacturing, testing, labeling, packaging, storing and distributing our product candidates ~~in partnership with~~ **. We do not own or operate any facilities for product manufacturing, testing, labeling, packaging, or storage. The facilities used by our** third- party contractors ~~. We do not own or operate any facilities for product manufacturing, testing, labeling, packaging, or storage. We are dependent on third parties~~ to manufacture **,** ~~,~~ **and** test ~~, label, package, store, and distribute the clinical and commercial supplies of~~ our ~~current and any future~~ product candidates **may be inspected by the FDA after we submit an EUA or a BLA to the FDA** . We have established a relationship with WuXi Biologics as our CDMO to manufacture our product candidates for clinical and commercial supply ~~. The facilities used by our third- party contractors to manufacture and test our product candidates may be inspected by the FDA after we submit an EUA or a BLA to the FDA~~ . We do not control the manufacturing process of, and are completely dependent on, our CDMO for compliance with the cGMP requirements. If our CDMO cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and / or maintain regulatory authorization or approval for our product candidates. In addition, we have limited control over the ability of our CDMO to maintain adequate quality control, quality assurance and qualified personnel, including their ability to adequately separate products within their multi- product manufacturing facilities to prevent cross- contamination. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to timely develop, obtain regulatory authorization or approval for or market our product candidates, if authorized or approved. If we are not able to meet market demand for any authorized or approved product or if we are not able to produce supply at low enough costs, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business, financial condition, results of operations and prospects. We ~~have engaged WuXi Biologics for development and generation of the production cell line starting material manufacturing for our product candidates. The cell line expression technology used to generate the cell line is a licensed technology. Only high- level information identifying the general nature of the control elements in the expression vector has been provided to us. Details of the expression technology have not been provided, nor has there been sufficient information provided to enable a freedom- to- operate assessment of the expression technology. In addition, we~~ currently rely **exclusively** on WuXi Biologics' China- based facilities for clinical supply and commercial supply. We will likely continue to rely on foreign CDMOs in the future. Foreign CDMOs may be subject to trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, or delay or prevent the shipment of material out of the foreign country to the U. S. **There is additional uncertainty as it is not known what actions, including the imposition of potential sanctions or tariffs, may be taken by the new U. S. presidential administration.** Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our partnerships in China, which could have an adverse effect on our business, financial condition, results of operations and prospects. Foreign CDMOs may also be the subject of U. S. legislation. For example, in late- 2023 and early- 2024, there was congressional activity, including the introduction of the BIOSECURE Act (H. R. 7085) in the House of Representatives **(which was passed in September 2024)** and a substantially similar Senate bill (S. 3558), which **, if enacted, would** discourage contracting with Chinese biotechnology companies, and specifically WuXi Apptec and its subsidiaries on the development or manufacturing of pharmaceutical products. If this legislation became law, or if a similar law were passed, it would have the potential to severely restrict the ability of U. S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies " of concern " without losing the ability to contract with, or otherwise receive funding from, the U. S. government. It is possible some of our contractual counterparties, including WuXi Biologics, could be impacted by the legislation described above. If WuXi Biologics or any of the other third parties that we engage to supply any materials or manufacture products for our preclinical tests and clinical trials should cease to continue to do so for any reason, we could experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us, or at all. In addition, if we are not able to obtain adequate supplies of our products or product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates, commercialize our

products and compete effectively. Further, our reliance on third parties for manufacturing, testing, labeling, packaging and storing our product candidates entails risks to which we would not be subject if we manufactured, tested, labeled, packaged and stored our product candidates ourselves, including: • inability to access sufficient manufacturing capacity on desired timelines; • inability of a third- party manufacturer to execute our manufacturing procedures and other logistical support requirements appropriately; • inability to negotiate additional manufacturing agreements with third parties under commercially reasonable terms, if at all; • breach, termination or nonrenewal of manufacturing agreements in a manner or at a time that is costly or damaging to us; • lack of ownership of the intellectual property rights in any improvements made by a third- party manufacturer in the manufacturing process for our product candidates; • a third- party manufacturer may gain knowledge from working with us that could be used to supply one of our competitors with a product that competes with ours; and • disruptions to operations of a third- party manufacturer or suppliers by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier. We **have engaged WuXi Biologics for development and generation of the production cell line starting material manufacturing for our product candidates. The cell line expression technology used to generate the cell line is a licensed technology. Only high- level information identifying the general nature of the control elements in the expression vector has been provided to us. Details of the expression technology have not been provided, nor has there been sufficient information provided to enable a freedom- to- operate assessment of the expression technology. We** cannot be sure that single- source suppliers for our manufacturing raw materials will remain in business, will not be subject to regulatory actions that impede our procurement of raw materials, or will not be purchased by one of our competitors or another company that is not interested in continuing to produce these raw materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier could be lengthy and we could experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, delays resulting in supply disruptions, diversion of resources or reduced manufacturing yields, any of which would adversely impact our business, financial condition and results of operations. Any of these events could lead to clinical trial delays or failure to obtain or maintain regulatory authorization or approval or impact our ability to successfully commercialize our product candidates, if authorized or approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure or total or partial suspension of production ~~. In July 2021, we entered into a license agreement with Biocon to combat COVID- 19 in Southern Asia. Under the license agreement, we will provide Biocon materials and know- how to manufacture and commercialize an antibody treatment based on adintrevimab in India and select emerging markets. Biocon' s ability to successfully manufacture in those territories may be restricted by foreign regulatory requirements~~ . We may seek collaborations with third parties for the discovery, development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. We may seek third- party collaborators for the discovery, development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the U. S. Our likely collaborators for any such arrangements include regional and national pharmaceutical companies and biotechnology companies. If we enter into any additional such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. For example, ~~our~~ **in July 2021, we entered into a license** agreement with Biocon ~~may not result~~ **to combat COVID- 19** in **Southern Asia. Under** the ~~successful development~~ **license agreement, we will provide Biocon materials** and **know- how to manufacture and** ~~commercialization~~ **commercialize** ~~of~~ an antibody treatment **based on adintrevimab in India and select emerging markets. However, our agreement with Biocon may not result in the successful development and commercialization of an antibody treatment** for COVID- 19 in India or other markets **. Biocon' s ability to successfully manufacture in those territories may be restricted by foreign regulatory requirements** . Collaborations involving our product candidates would pose the following risks to us: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • we could grant exclusive rights to our collaborators that would prevent us from collaborating with others; • product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; • a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe

the intellectual property rights of third parties, which may expose us to litigation and potential liability; and • collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the European Commission or similar regulatory authorities outside the U. S., the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue. The third parties upon whom we depend may be adversely affected by earthquakes, wildfires or other natural and manmade disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure, armed conflict, or other natural or manmade accidents or incidents that result in the third parties upon whom we depend from being unable to fully utilize their facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event prevented the third parties upon whom we depend from using all or a significant portion of their manufacturing facilities, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. Unforeseen natural or manmade accidents or incidents, such as freezer failure, natural disasters or theft, could also result in loss of cell line starting material. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If the third parties on which we rely are unable to operate their facilities because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects. Risks Related to Our Intellectual Property If we are unable to obtain, maintain and enforce patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates **, including PEMGARDA,** and technologies. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the U. S. and in other countries with respect to our proprietary technology and product candidates. The risks associated with patent rights generally apply to patent rights that we in- license now or in the future, as well as patent rights that we may own now or in the future. We currently own three issued U. S. patents with claims directed to adintrevimab, ADG10, and methods of use of adintrevimab, alone or in combination with ADG10 (an antibody- based product candidate previously considered for potential use in combination with adintrevimab for the treatment and prevention of COVID- 19), respectively. In addition, although we own a number of pending patent applications, we may not be successful in prosecuting our filed patent applications to obtain issuance of additional patents. Accordingly, there can be no assurance that we will be able to obtain patent protection for our product candidates. Our pending Patent Cooperation Treaty (" PCT ") patent applications, are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. Furthermore, our pending U. S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non- provisional U. S. patent application within one year of filing of the U. S. provisional patent application with the USPTO. If we do not timely file any national stage patent applications or non- provisional U. S. patent

applications, we may lose our priority date with respect to our PCT and provisional U. S. patent applications, and any patent protection on the inventions disclosed in such 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. In addition, the coverage claimed in any such patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Failure to obtain and maintain such issued patents could have a material adverse effect on our ability to develop and commercialize our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our resulting or granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product, that would be competitive with one or more of our product candidates. There is no assurance that all the potentially relevant prior art relating to our patent and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Since patent applications in the U. S. and most other countries are confidential for a period of time after filing, we cannot be certain that we or our future licensors were the first to file any patent application related to our product candidates and technologies. We additionally cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the " first- to- file " laws in the U. S., such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and, even if issued, may be challenged and invalidated or rendered unenforceable. Additionally, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in courts or patent offices in the U. S. and abroad. For example, we may be subject to a third- party submission of prior art to the USPTO, challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent' s issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Any successful challenge to any patents owned by or licensed to us after patent issuance could put one or more of our owned or in- licensed patents at risk of being invalidated or interpreted narrowly and could deprive us of rights necessary for the successful commercialization of any of our product candidates and technologies that we may develop. Even if they are unchallenged or such third- party challenges are unsuccessful, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates and technologies or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent and patent applications we hold, obtain or pursue with respect to our product candidates and technologies is challenged, or if they fail to provide meaningful exclusivity for our product candidates and technologies, it could threaten our ability to commercialize our product candidates and technologies. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection, if approved, would be reduced. The patent prosecution process is expensive and time- consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost, in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection. Moreover, depending on the terms of any future in- licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in- licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Any of the foregoing could have an adverse impact on our business and results of operations. If we are unable to protect the confidentiality of trade secrets, our business and competitive position would be harmed. In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know- how that is not or may not be patentable or that we or our partner (s) elect not to patent. Whether proprietary information, data and processes were developed internally, through collaboration partnering, or licensed from one or more third parties, we seek to protect them, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. Although these agreements are designed to protect proprietary information, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to trade secrets or independently develop substantially equivalent information and techniques. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to proprietary know- how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed with all third parties who may have helped to develop our intellectual property or who had access to proprietary information, or that our agreements will not be breached. If any of the parties to these confidentiality agreements breaches or violates the terms of such agreements, we may not have adequate remedies for any such breach or violation, and we could lose trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time- consuming, and the outcome is unpredictable. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U. S. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U. S. and abroad. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we

may have insufficient recourse against third parties for misappropriating the trade secret. Trade secrets and know- how can be difficult to protect as trade secrets and know- how will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Moreover, our competitors and other third parties may independently develop knowledge, methods and know- how equivalent to our trade secrets. Competitors and other third parties could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or violate our intellectual property rights, design around our protected technology or develop their own technologies that fall outside of our intellectual property rights. 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, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets and proprietary know- how were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA' s disclosure policies may change in the future. If we are unable to prevent material disclosure of the non- patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch- Waxman Amendments and similar non- U. S. legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed. Patents have a limited lifespan. In the U. S., the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic and other competing medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and 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 receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, fail to exercise due diligence during the testing phase or regulatory review process, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension, or if the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, which could have a material adverse effect on our business. We are a party to an assignment and license agreement, a collaboration agreement and a platform transfer agreement with Adimab, pursuant to which we are obligated to make payments upon achievement of milestone events and royalties. If these agreements are terminated, our business and prospects will be materially and adversely affected. We are party to the Adimab Assignment Agreement with Adimab, under which Adimab has assigned to us its rights, title and interest in and to certain of its coronavirus- specific antibodies, including modified or derivative forms thereof, and related intellectual property. Pursuant to the Adimab Assignment Agreement, Adimab additionally granted us a non- exclusive, worldwide, royalty-bearing sublicensable license to certain of its platform patents and technology for the development, manufacture and commercialization of the CoV Antibodies and pharmaceutical products containing or comprising one or more CoV Antibodies for all indications and uses, with the exception of certain diagnostic uses and use as a research reagent. Under the Adimab Assignment Agreement, we are obligated to use commercially reasonable efforts to achieve specified development and regulatory milestones for subject products in certain major markets and to commercialize a subject product in any country in which we obtain marketing approval. This agreement additionally contains obligations that require us to make payments in the event certain milestone events are achieved and royalty payments on net sales of any subject products, in accordance with the Adimab Assignment Agreement, beginning upon the first commercial sale of a subject product in accordance with the Adimab Assignment Agreement, on a product- by- product and country- by- country basis, for a period ending on the later of (i) 12 years after the first commercial sale of such product in such country and (ii) the expiration of the last valid claim of a patent covering such product in such country. We are also party to the Adimab Collaboration Agreement with Adimab for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Collaboration Agreement, we could collaborate with Adimab on research programs for a specified number of targets selected by us within a specified time

period. Under the Adimab Collaboration Agreement, Adimab granted us a worldwide, non- exclusive license to certain of its platform patents and technology and antibody patents to perform our responsibilities during the Evaluation Term. In addition, we granted Adimab a license to certain of our patents and intellectual property solely to perform Adimab' s responsibilities under the research plans. Under the Adimab Collaboration Agreement, we have an exclusive option, on a program- by- program basis, to obtain licenses and assignments to commercialize selected products containing or comprising antibodies directed against the applicable target, which option may be exercised upon the payment of a specified option fee for each program. Upon our exercise of an option, Adimab will assign us all right, title and interest in the antibodies of the optioned research program and will grant us a worldwide, royalty- free, fully paid- up, non- exclusive, sublicensable license under the Adimab platform technology for the development, manufacture and commercialization of the antibodies for which we have exercised our options and products containing or comprising those antibodies. We are obligated to use commercially reasonable efforts to develop, seek marketing approval for, and commercialize one product that contains an antibody discovered in each optioned research program. The Adimab Collaboration Agreement additionally contains obligations that require us to make payments in the event certain milestone events are achieved and royalty payments on net sales of subject products, in accordance with the Adimab Collaboration Agreement, on a product- by- product and country- by- country basis, for a period ending on the later of (i) 12 years after the first commercial sale of such product in such country and (ii) the expiration of the last valid claim of any patent claiming composition of matter or method of making or using any antibody identified or optimized under the Adimab Collaboration Agreement in such country. We are also party to the Adimab Platform Transfer Agreement with Adimab under which we were granted the right under certain intellectual property of Adimab to practice certain elements of Adimab' s platform technology, including B- cell cloning using Adimab' s proprietary yeast cell lines and other antibody optimization libraries, trade secrets, protocols and software of Adimab, to discover, engineer and optimize antibodies. We do not have access to Adimab' s proprietary discovery libraries. We were also granted the right under certain intellectual property of Adimab to research, develop, make, sell and exploit such antibodies and products containing such antibodies. The Adimab platform has been transferred to us in accordance with the terms of the Adimab Platform Transfer Agreement. During the first four years of the Adimab Platform Transfer Agreement, we owe a fixed annual fee to Adimab, which allows us to receive material improvements to the platform technology, including materially improved antibody optimization libraries, updates that provide new functionality to the platform, and software upgrades, from Adimab through June 2027. After such time, until June 2042, unless terminated earlier, we have the option to receive additional material improvements to the platform technology from Adimab, subject to a commercially reasonable fee to be negotiated by the parties. The Adimab Platform Transfer Agreement also contains obligations that require us to make payments to Adimab in the event certain specified development and regulatory milestone events are achieved and royalty payments on net sales of subject products, in accordance with the Adimab Platform Transfer Agreement, on a product- by- product and country- by- country basis, for a period ending on the later of (i) 12 years after the first commercial sale of such product in such country and (ii) the expiration of the last valid claim of a program antibody patent for covering the program antibody contained in such product in such country. While we are building our internal capabilities in order to discover and develop mAb candidates, our business continues to be reliant upon the intellectual property rights assigned and licensed to us under the Adimab Assignment Agreement, the Adimab Collaboration Agreement and the Adimab Platform Transfer Agreement. If we materially breach the Adimab Assignment Agreement, the Adimab Collaboration Agreement or the Adimab Platform Transfer Agreement, our licenses under the Adimab Assignment Agreement, the Adimab Collaboration Agreement and the Adimab Platform Transfer Agreement can be terminated, we can be required to return to Adimab the assigned patent rights and any patents or patent applications that claim priority to such patents, our rights to develop and commercialize our product candidates will be adversely affected, and we could be found liable for substantial monetary damages. If the Adimab Assignment Agreement, the Adimab Collaboration Agreement or the Adimab Platform Transfer Agreement is terminated as a result of our breach or otherwise, our business and prospects will be materially and adversely affected. Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the 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 rely on licensed intellectual property rights and intend to periodically explore a variety of additional possible strategic collaborations or licenses in an effort to gain access to additional product candidates, technologies or resources. At this time, we cannot predict what form such strategic collaborations or licenses might take in the future. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations and licenses can be complicated and time- consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations or licenses because of the numerous risks and uncertainties associated with establishing them. Any delays in entering into new strategic collaborations or licenses 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. Our current and future collaborations and licenses could subject us to a number of risks, including: • we may be required to undertake the expenditure of substantial operational, financial and management resources; • we may be required to comply with various development, diligence, commercialization and other obligations and meet development timelines, or exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses (for example, under the Adimab Assignment Agreement, we are required to use commercially reasonable efforts to achieve specified development and regulatory milestones for products in certain major markets and to commercialize a product in any country in which we obtain marketing approval); • we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company; • we may be required to assume substantial actual or contingent liabilities; • we may not be able to control the amount and timing of resources that our strategic

collaborators devote to the development or commercialization of our product candidates; • we may not have the right to control the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license, and we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business (for example, we have no rights to control the preparation, filing, prosecution or maintenance of the patents licensed to us under Adimab' s antibody discovery and optimization platform technology under the Adimab Assignment Agreement); • strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so; • strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing; • strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs; • strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenue from these products; • disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management' s attention and consumes resources; • strategic collaborators may experience financial difficulties; • strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation; • business combinations or significant changes in a strategic collaborator' s business strategy may adversely affect a strategic collaborator' s willingness or ability to complete its obligations under any arrangement; • strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and • strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates. Disputes may arise with respect to our current or future licensing agreements, including in connection with any of the forgoing, and, in spite of our efforts, our current and future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. Our license agreements are, and future license agreements are likely to be, 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. Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and licensed patents, and the enforcement or defense of our licensed patents or future owned patents. Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the U. S. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the U. S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy- Smith America Invents Act (the " Leahy- Smith Act ") was signed into law. The Leahy- Smith Act included a number of significant changes to U. S. patent law. These included provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review and derivation proceedings. Finally, the Leahy- Smith Act contained new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Further, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our 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 actions 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 have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability

to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U. S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U. S. and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the U. S. and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. As one example, in Europe, a new unitary patent system became effective in June 2023, which may significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (" UPC "). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. We may be involved in lawsuits to protect or enforce our future patents, the patents of our licensors or our other intellectual property or proprietary rights, which could be expensive, time consuming and unsuccessful and our future issued patents and the patents of our licensors covering our product candidates could be found invalid or unenforceable. Competitors or other third parties may infringe, misappropriate or otherwise violate the patents of our licensors or any patents issued as a result of our pending or future patent applications. To counter infringement, misappropriation or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable or is not infringed, or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our licensed or future owned patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our owned or licensed patent applications at risk of not yielding an issued patent. If we 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 or product candidate is invalid and / or unenforceable. In patent litigation in the U. S., counterclaims alleging invalidity and / or unenforceability are common, 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 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 U. S. or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, inter partes review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings, nullity proceedings or litigation or invalidation trials or invalidation proceedings). Such proceedings could result in revocation of or amendment to our future patents in such a way that they no longer cover our product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patent applications, should they issue as patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Interference or derivation proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions or inventorship (and possibly also ownership) of inventions with respect to our patent applications or resulting patents, or patent applications or resulting patents of third parties. For example, we were notified in October 2020 that a third party claimed that one of its employees should be listed as an inventor on certain of our patent applications claiming SARS- COV- 2 binding antibodies or their preparation; however, we believe such claim, if valid, would be limited to only a predecessor antibody to adintrevimab and, in any event, is without merit. The entity that assigned to us the relevant patent applications is required to indemnify us with respect to any potential financial ramifications relating to this claim. However, an unfavorable outcome in this claim or any other inventorship or ownership dispute could result in the loss of our exclusive rights in our technology and the associated intellectual property rights, require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Furthermore, any successful claim of inventorship by a third party could result in the loss of priority for our patent applications, potentially resulting in subsequently filed third- party patent applications having priority over our patent applications and thereby precluding our ability to obtain patent protection for the inventions claimed in our patent applications. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U. S. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. An adverse result in any litigation or defense proceedings could put one or more of our or our licensors' patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our

business. 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, 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 greater financial resources and more mature and developed intellectual property portfolios. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any of the foregoing could materially adversely affect our business, results of operations and financial condition. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the U. S. and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, WuXi Biologics has provided only high- level information to us identifying the general nature of the licensed control elements in the expression vector used in the production cell line starting material for product manufacturing. Details of the expression technology have not been provided, nor has there been sufficient information provided to enable a freedom- to- operate assessment of the expression technology. We therefore cannot be sure that we have licensed all intellectual property rights that are relevant to or necessary for the commercialization of our product candidates, and a third party may claim that our development or commercialization of our product candidates infringes its intellectual property rights. We could be required to acquire or obtain a license to such intellectual property from such third parties, and we may be unable to do so on commercially reasonable terms or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights, we may be required to redesign our manufacturing process for our product candidates, which may not be feasible on a technical or commercial basis in a timely manner, and we may have to delay or abandon development of our product candidates, which could have a material adverse effect on our business. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U. S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant third- party patents may negatively impact our ability to develop and market our products. We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates. A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The licensing or acquisition of third- party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to in- license any such necessary intellectual property, it could be on a non- exclusive basis, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and we also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to redesign our product candidates, which may not be feasible on a technical or commercial basis, and we may have to delay or abandon development of the relevant program or product candidate, which could have a material adverse effect on our business. 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. Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents, trademarks, and proprietary rights of third parties. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There is a substantial amount of litigation involving patents, trademarks, and other intellectual property rights in the biotechnology and pharmaceutical industries, including infringement lawsuits, interferences, derivation proceedings, post grant reviews, inter partes reviews, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and there may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates and technologies. Third parties, including our competitors may initiate legal proceedings against us alleging that we are infringing, misappropriating or otherwise violating their patents, trademarks, or other intellectual property rights. We cannot provide any assurance that our product candidates do not infringe, misappropriate or otherwise violate other parties' patents, trademarks, or other proprietary rights, and competitors or other parties may assert that we infringe, misappropriate or otherwise violate their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product

candidates, including oppositions, interference proceedings, reexaminations, post- grant review, inter partes review, or derivation proceedings before the USPTO in the U. S. or any equivalent regulatory authority in other countries. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our product candidates. In order to successfully challenge the validity of any U. S. patents asserted against us in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such U. S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the U. S. and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third- party patents or patent applications, or we may incorrectly conclude that a third- party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that one of our product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. In addition, third parties may obtain patents in the future and claim that our product candidates or technologies infringe upon these patents. Moreover, we may face patent infringement claims from non- practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit. If we are found to infringe, misappropriate or otherwise violate a third party' s valid intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. For example, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if a license can be obtained on acceptable terms, the rights may be non- exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease developing, manufacturing and commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the patent at issue. We may also be required to indemnify collaborators or contractors against such claims. A finding of infringement, misappropriation or other violation of third- party intellectual property rights could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management' s attention. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in- license needed technology. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares. 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 be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. We may be subject to claims challenging the inventorship or ownership of our future patents and other intellectual property. We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents issued as a result of our pending or future applications, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our

policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self- executing or the assignment agreements may be breached, and litigation may be necessary to enforce our rights or to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We rely on third parties to manufacture our product candidates, and we collaborate with additional third parties for the development of such product candidates. We therefore must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third- party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know- how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time- consuming, and the outcome is unpredictable. In addition, courts outside the U. S. are sometimes less willing to protect trade secrets. We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world. Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors have patent protection, but enforcement rights are not as strong as those in the U. S. or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Additionally, unforeseen global events such as the conflict between Russia and Ukraine, and sanctions relating to these events could affect our ability to file, prosecute, and defend patents and patent applications in those jurisdictions. Further, legal or regulatory action by various stakeholders or governments could potentially result in us not seeking intellectual property protection for or agreeing not to enforce or being restricted from enforcing intellectual property related to our products. **For example, there were** ~~Discussions~~ **discussions** ~~are ongoing~~ at the World Trade Organization (the " WTO ") regarding the role of intellectual property in the context of the COVID- 19 ~~pandemic~~ response **, including** ~~. This includes~~ a proposal that would release WTO members from their obligation under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights to grant and enforce various types of intellectual property protection on health products and technology in relation to the treatment of COVID- 19. In addition, we or our licensors may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the U. S., but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U. S. and Europe and many companies have

encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, especially those relating to life sciences, which could make it difficult for us to stop the infringement, misappropriation or other violation of our future patents or marketing of competing products in violation of our proprietary rights generally. For example, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Moreover, our and our licensors' ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Proceedings to enforce our or our licensors' patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensors at risk of not issuing as patents, and could provoke third parties to assert claims against us. We and our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license from third parties. Some countries also 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~~ therapeutic in those countries. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations and prospects may be adversely affected. For example, our license agreement with Biocon pursuant to which we will provide Biocon materials and know- how to manufacture and commercialize an antibody treatment based on adintrevimab in India and select emerging markets may also expose us to risks related to enforcement of our intellectual property rights. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and / or applications will be due to be paid to the USPTO and various government patent agencies outside of the U. S. over the lifetime of our owned and licensed patents and / or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non- U. S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patent and patent applications that we own, and we rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business. We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from the drugs of our competitors. We also expect to rely on trademarks to protect our company name. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. We currently have trademark applications pending in the U. S. and in certain foreign jurisdictions, but we have no issued trademark registrations in the U. S. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. ~~In~~ **For example, in** October 2023, Ipsen Biopharm, LTD **(" Ipsen ")** and its affiliates filed oppositions against our trademark applications for **"** INVIVYD **"** in the USPTO based on Ipsen' s registered trademark for the oncology drug **"** ONIVYDE **"** . ~~Prior to that, in July 2023,~~ **We resolved this issue by entering into a coexistence agreement with** Ipsen **in which Ipsen withdrew their** ~~and its licensee Les Laboratoires Servier filed~~ oppositions **of the** ~~against our trademark applications for~~ INVIVYD **mark** ~~in Switzerland, United Kingdom, European Union,~~ and **we agreed** ~~Australia, likewise based on ONIVYDE. As of November 1, 2023, action has been suspended in all proceedings~~ to **limit** ~~allow for settlement negotiations. The outcome of these settlement negotiations or~~ **our use of INVIVYD to a " house mark** ~~, in the alternative, the opposition proceedings, is uncertain~~ . **"** If we are found to infringe the trademark rights of **a** ~~Ipsen, its licensee, or another~~ third party, we could be forced to rebrand our company or our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. In the event such infringement is found to have caused commercial harm, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the trademark at issue. Our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively, and our competitive position, business, financial condition, results of operations and prospects may be significantly harmed. Moreover, any name we propose to use with our product candidates in the U. S. must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA

objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Any of the foregoing events may have a material adverse effect on our business. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative: • others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of any of our patents, should they issue; • an in- license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor; • we or our collaborators might not have been the first to make the inventions covered by our future issued patents or our pending patent applications; • we or our collaborators might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own or in- license may be held invalid or unenforceable as a result of legal challenges by our competitors; • issued patents that we own or in- license may not provide coverage for all aspects of our product candidates in all countries; • our competitors might conduct research and development activities in the U. S. 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 then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; 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, results of operations and prospects. Risks Related to Legal and Regulatory Compliance Matters We received an EUA for PEMGARDA, which the FDA would be required to revoke if HHS determines that emergency use is no longer warranted, which would adversely impact our ability to market PEMGARDA in the United States. The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat or prevent serious or life- threatening diseases or conditions when there are no adequate, approved and available alternatives. On March 22, 2024, we received an EUA from the FDA for PEMGARDA for the pre- exposure prophylaxis (prevention) of COVID- 19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate- to- severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID- 19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS- CoV- 2. The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID- 19 pandemic under Section 564 (b) (1) of the FDCA, unless the declaration is terminated or authorization revoked sooner. Because the FDA is required to revoke an EUA if HHS determines that emergency use is no longer warranted, we cannot predict how long our EUA for PEMGARDA will remain in place. If the FDA terminates or revokes our EUA for PEMGARDA prior to us having pursued and received regulatory approval to commercialize PEMGARDA through a traditional approval pathway, we would be required to cease our commercialization efforts, which would substantially and negatively impact our business. Our relationships with customers, healthcare providers, including physicians, and third- party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims 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 U. S. 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 federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute, the federal civil and criminal false claims laws, the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals **and patients** . In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration ~~(including any kickback, bribe or rebate)~~ , directly or indirectly, overtly or covertly, in cash or in kind in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any ~~good, facility,~~ item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term " remuneration " has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation; • the federal civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of government funds, including from Medicare, Medicaid and other government payors, that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes " any request or demand " for money or property presented **for payment of** ~~to the U.~~

~~S. federal~~ government **funds** . Several pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for **a variety of alleged misconduct, including, for example,** allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. The government may deem companies to have " caused " the submission of false or fraudulent claims by, for example, ~~because of~~ the companies' marketing of products for unapproved, and thus non-reimbursable, uses. In addition, the government may assert that a claim, including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on " covered entities, " ~~including~~ certain healthcare providers, health plans, healthcare clearinghouses, and their respective " business associates, " **certain persons or entities** that create, receive, maintain or transmit **protected** ~~individually identifiable~~ health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of **protected** ~~individually identifiable~~ health information **. Other** ~~, as well as~~ analogous state and foreign laws ~~that~~ govern the privacy and security of health information in some circumstances **. Additionally** , **numerous federal and state laws, including state security breach notification laws, and federal and state consumer protection and privacy laws, (including, for example, Section 5 of the FTC Act and the FTC Health Breach Notification Rule, and the CCPA, as amended by the CPRA) govern the collection, use and disclosure of personal information.** ~~many~~ **Many** of ~~which~~ **these laws** differ from each other in significant ways and ~~often are not preempted by HIPAA,~~ thus ~~complicating~~ **complicate** compliance efforts; • HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services **, including those by private payors** . Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children' s Health Insurance Program, with specific exceptions, to report annually to CMS, information related to: (i) payments or other " transfers of value'' made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members; and • analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives. 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. 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, 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, any of which could harm our business. 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 the 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. ~~Even if~~ **If and when** we obtain regulatory authorization or approval for a product candidate, such products will remain subject to ongoing regulatory oversight, which may result in significant additional expense. ~~Even if~~ **If and when** we obtain any regulatory authorization or approval for our product candidates, such as PEMGARDA, which received an EUA from the FDA in March 2024, they will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record- keeping and submission of safety and other post- market information, among other things. For example, we will be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our authorized or approved products to regulatory authorities along with other periodic reports. Any regulatory approvals that we receive for a product candidate may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post- marketing testing and surveillance studies, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post- marketing study or failure to complete such a study could result in the withdrawal of marketing approval. Additionally, the FDA has expected that companies

that receive an EUA for COVID- 19 antibodies will proceed to licensure of their products under a BLA, which, if required of us by the FDA with respect to any product candidate for which we receive an EUA, would be time- consuming and expensive. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will also have to comply with requirements concerning advertising and promotion for our products, including any limitations on advertising and promotion for a product authorized under an EUA, such as PEMGARDA. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have authorization or approval, commonly known as off- label promotion. If one or more of our products were granted an EUA, such as PEMGARDA, there are additional limitations the FDA places upon manufacturers as to promotional communications and conditions the FDA imposes on manufacturers as to permissible form and substance and process for regulatory submission of promotional communications, which conditions are subject to change. If an EUA is granted, we will rely on the FDA or other applicable regulatory authority policies and guidance governing products authorized in this manner in connection with the marketing and sale of our product. If these policies and guidance change unexpectedly and / or materially or if we misinterpret them, potential sales of our product could be adversely impacted. Furthermore, the FDA may terminate an EUA, including our EUA for PEMGARDA, if safety issues or other concerns about our product, such as loss of neutralizing activity against dominant circulating SARS- CoV- 2 variants, arise or if we fail to comply with the conditions of authorization. The holder of an approved BLA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. A company that is found to have improperly promoted off- label uses of their products may be subject to significant civil, criminal and administrative penalties. In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in an EUA, BLA or foreign marketing application. We need to monitor adverse events resulting from the use of our products candidates, as do the regulatory authorities, and we file periodic reports with the authorities concerning adverse events. The FDA, the competent authorities of the European Union Member States on behalf of the EMA, and the competent authorities of other European countries also periodically inspect records related to safety reporting. The EMA' s Pharmacovigilance Risk Assessment Committee may propose to the Committee for Medicinal Products for Human Use that a marketing authorization holder be required to take specific steps or advise that the existing marketing authorization be varied, suspended or revoked. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring variation, suspension or withdrawal of marketing authorization, or suspension of manufacturing, or imposition of financial penalties or other enforcement measures. If we fail to comply with applicable regulatory requirements following authorization or approval of a product candidate, a regulatory authority may: • issue an untitled letter or warning letter asserting that we are in violation of the law; • seek an injunction or impose administrative, civil or criminal penalties or monetary fines; • suspend or withdraw regulatory authorization or approval; • suspend any ongoing clinical trials; • refuse to approve a pending marketing application or supplement to an approved application or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners; • restrict the marketing or manufacturing of the drug; • seize or detain the drug or otherwise require the withdrawal of the drug from the market; • refuse to permit the import or export of products or product candidates; or • refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize PEMGARDA or any future product candidates and harm our business, financial condition, results of operations and prospects. Despite obtaining authorization under an EUA for PEMGARDA in the U. S., we may never obtain authorization or approval for or commercialize PEMGARDA or any other product candidate in any other jurisdiction, which would limit our ability to realize any of their full market potential. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. In addition, in order to distribute PEMGARDA or any other product candidates, if authorized or approved, we will need to secure and maintain required state licenses. Authorization or approval by the FDA in the U. S. does not ensure authorization or approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain authorization or approval in one jurisdiction may negatively impact our ability to obtain authorization or approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Authorization and approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory authorization or approval could result in difficulties and increased costs for us 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 products in those countries. We do not have any product candidates authorized or approved for sale in any jurisdiction other than PEMGARDA in the U. S. under an EUA, including in international markets, and we do not have experience in obtaining regulatory authorization or approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required authorizations or approvals, or if regulatory authorizations or approvals in international markets are delayed, our market opportunity will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations. In the U. S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes

regarding the healthcare system that could prevent or delay regulatory authorization or approval of product candidates, restrict or regulate post- authorization or post- approval activities, and affect our ability to profitably sell any product candidates for which we obtain regulatory authorization or approval. Among policy makers and payors in the U. S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the U. S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. The ACA substantially changed the way healthcare is financed by both the government and private insurers and significantly impacts the U. S. pharmaceutical industry. The ACA, among other things contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. There have been judicial and congressional challenges to certain aspects of the ACA and its implementing regulations as well as efforts to modify them or alter their interpretation or implementation. While the U. S. Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act included a provision that repealed the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " In addition, the 2020 federal spending package permanently eliminated the ACA- mandated " Cadillac " tax on high- cost employer- sponsored health coverage and also eliminated the health insurer tax. Additional legislative changes, regulatory changes and judicial challenges related to the ACA remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. It is unclear how any efforts to modify, or invalidate the ACA, its implementing regulations, or portions thereof, and other reform measures that may be adopted in the future will affect our business. Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers ~~of 2 % per fiscal year~~ pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA and the Infrastructure Investment and Jobs Act, will remain in effect through 2031. Under current legislation ~~, after a brief pause and reduction to 1 % due to COVID- 19~~ , sequestration is currently set at 2 % **and will increase to 2. 25 % for the first half of fiscal year 2030, to 3 % for the second half of fiscal year 2030, and to 4 % for the remainder of the sequestration period that lasts** through the first ~~7~~ **six** months of **fiscal year** ~~2032~~ **2031** . The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, effective January 1, 2024. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding or otherwise have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations. Additionally, there has been heightened governmental scrutiny in the U. S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. The Inflation Reduction Act of 2022 (the " IRA "), among other things, permits the **HHS** ~~U. S. Department of Health and Human Services~~ to negotiate prescription drug prices with companies, subject to a specified cap, for Medicare units of a specified number of certain **FDA approved or licensed** brand name drugs or biologics without generic or biosimilar competitors each year, with such prices first set to take effect starting in 2026 for such products reimbursed under Medicare Part D and in 2028 for products reimbursed under Medicare Part B. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and / or a civil monetary penalty. The IRA further makes several changes to the Medicare Part D benefit, including a limit on annual out- of- pocket costs, and a change in manufacturer liability under the program **for an applicable drug** that could negatively affect the profitability of our product candidates. Failure to comply with requirements under the Part D benefit redesign is subject to a civil monetary penalty. The IRA also prohibits Medicare Part D plans from imposing cost- sharing for certain vaccines that are recommended by the Advisory Committee on Immunization Practices. Congress may continue to consider drug pricing as part of other reform initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. **Additionally, some individual states have begun establishing Prescription Drug Affordability Boards to review high- cost drugs and, in some cases, set upper payment limits.** 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 drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. It is also possible that additional governmental action will be taken in response to the COVID- 19 pandemic. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our product candidates. We cannot determine how changes in regulations, statutes, policies or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require: • additional clinical trials to be conducted prior to obtaining authorization or approval; • changes to

manufacturing methods; • recalls, replacements or discontinuance of one or more of our products, if authorized or approved; and • additional recordkeeping. Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory authorizations or approvals for our products would harm our business, financial condition and results of operations. Risks Related to Employee Matters and Managing Our Growth Our future success depends on our ability to **attract and** retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the management, scientific, clinical, manufacturing, commercial, financial, legal and business development expertise of our executive officers. ~~Each of our executive~~ **Executive** officers may ~~currently~~ terminate ~~their~~ employment with us at any time **, and the ability to attract a key executive to replace that position and the ability to retain additional key executives are critical to our success** . We do not maintain " key person " insurance for any of our executives or employees. **Since May 2024, William Duke, Jr., our Chief Financial Officer, has served as our " principal executive officer. " Mr. Duke assumed such role following the separation from Invivyd of our previous Chief Executive Officer and Interim Chief Executive Officer and is expected to continue to serve until a permanent successor can be identified. Executive leadership transition periods can often be difficult and may result in changes in leadership strategy and style. There may be organizational changes or changes in business strategy in connection with any future Chief Executive Officer transition, and we can provide no assurances that any such changes will be beneficial or will have the desired impact on the company.** Recruiting and retaining qualified scientific, clinical, manufacturing, and commercialization personnel, including market access, marketing and sales personnel, are also critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory authorization or approval of, and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating and executing our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. We also rely on contractors to support the sales, market access and medical affairs activities for commercialization and scientific exchange. If we are unable to continue to attract and retain high quality personnel and engage high quality contractors, our ability to pursue our growth strategy and achieve our business objectives will be limited. Adimab owns a significant percentage of our common stock, will be able to exert significant influence over matters subject to stockholder approval and may have interests that conflict with those of our other stockholders. Adimab is currently our largest stockholder and beneficially owns approximately ~~19~~ **18** . ~~7~~ **1** % of the voting power of our outstanding common stock ~~according to~~ **based on information provided about Adimab' s ownership in** a Schedule 13D Amendment filed by Adimab on January 22, 2024 ~~, which reported ownership as of January 19, 2024~~ . As such, Adimab has the ability to substantially influence us through this ownership position. For example, Adimab, acting together with a small number of our other large stockholders, will be able to control elections of directors, amendments of our organizational documents or approval of any merger, amalgamation, sale of assets or other major corporate transaction. Any transferees or successors of all or a significant portion of Adimab' s ownership in us will be able to exert a similar amount of influence over us through their ownership position. Adimab' s interests may not always coincide with our corporate interests or the interests of our other stockholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other stockholders. So long as it continues to own a significant portion of our outstanding voting securities, Adimab will continue to have considerable influence in all matters that are subject to approval by our stockholders. We may expand our clinical development and regulatory capabilities and have implemented sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. Depending on our development progress, we may experience growth in the number of our employees and the scope of our operations, particularly in the areas of research and discovery, clinical product development, regulatory affairs, ~~manufacturing~~ and sales, marketing and distribution. To manage our future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit, train and retain qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit, train and retain such qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, CDMO, suppliers and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, CDMO, suppliers and vendors may engage in misconduct, including intentional, reckless and / or negligent conduct that violates civil, criminal or administrative laws or regulations, including fraudulent conduct or other illegal activity. Misconduct by these parties could include conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties 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. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from 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. Risks Related to Ownership of Our Common Stock and Our Status as a Public Company ~~An active trading market for our common stock may not continue to be developed or sustained. Prior to the IPO, there was no public market for our common stock. Although our common stock is listed on the Nasdaq Global Market, an active trading market for our common stock may not continue to develop or be sustained, it may be difficult for you to sell shares at an attractive price or at all.~~ The trading price of the shares of our common stock has been and may continue to be volatile, and purchasers of our common stock could incur substantial losses. Our stock price may be volatile. Since the IPO and through March 12, ~~2024~~ **2025**, our common stock has traded at prices ranging from $ 0. ~~98~~ **35** to $ 78. 82 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including: • the commercial performance of PEMGARDA; • our ability to ~~leverage our INVYMAB platform approach to~~ timely identify, develop, obtain authorization or approval for, and commercialize mAbs ~~on~~ **in** a **manner** ~~perpetual basis~~ that keeps pace with viral evolution; • the timing, progress and results of our clinical trials or the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates; • the timing of our regulatory filings for our product candidates, and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s receipt and review of such filings, including without limitation the FDA' s declination to accept or review an EUA application submission or an issuance of a " refusal to file " letter or a request for additional information; • our ability to maintain our **existing** EUA for PEMGARDA, and the ~~receipt~~ **scope and timing** of any **amendments** ~~additional or amended EUAs from the FDA for PEMGARDA and the timing thereof~~ **thereto**; • delays in or termination of clinical trials; • adverse regulatory decisions, including failure to receive **any requested amendment to our existing EUA for PEMGARDA, or failure to receive** regulatory authorization or approval of ~~our~~ **any other** product ~~candidates~~ **candidate**; • serious safety concerns related to the use of PEMGARDA or any other product candidate; • changes in financial estimates by us or by any equity research analysts who might cover our stock; • conditions or trends in our industry; • changes in the market valuations of similar companies; • announcements by our competitors of new product candidates or technologies, or the results of clinical trials or regulatory decisions; • stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry; • publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; • announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures; • our relationships with our collaborators; • announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; • investors' general perception of our company and our business; • recruitment or departure of key personnel; • **failure to comply with listing requirements of The Nasdaq Stock Market (" Nasdaq "); •** overall performance of the equity markets; • trading volume of our common stock; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including patent or stockholder litigation; • changes in the structure of healthcare payment systems; • general political and economic conditions; and • other events or factors, many of which are beyond our control. The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations, including as a result of the COVID- 19 pandemic, the ongoing conflict between Russia and Ukraine, increases in inflation rates ~~and~~ **,** disruptions to global supply chain **or other macroeconomic factors**, that have often been unrelated or disproportionate to the prospects of the issuer and which have resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects ~~. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the COVID- 19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance~~. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock. In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources from our business. For example, on January 31, 2023, a securities class action lawsuit captioned Brill v. Invivyd, Inc., et. al., Case No. 1: 23- CV- 10254- LTS, was filed against us and certain of our former officers in the U. S. District Court for the District of Massachusetts. The **lawsuit** ~~complaint, as~~ **was** ~~amended~~ **dismissed with prejudice in September 2024. However**, ~~alleges violations~~ **we may be the target** of ~~Sections 10~~ **similar litigation in the future. There can be no assurance that we will continue to be able to comply with the continued listing standards of Nasdaq. Our common stock is listed on the Nasdaq Global Market, and we are therefore**

**subject to its continued listing requirements, including requirements with respect to the market value of publicly- held shares, market value of listed shares, minimum bid price per share, and minimum stockholders' equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements and are unable to timely regain compliance, we may be delisted from the Nasdaq Global Market. For example, on December 27, 2024, we received a letter from Nasdaq notifying us that, because the closing bid price for our common stock had closed below $ 1. 00 per share for 30 consecutive business days, we no longer complied with the minimum bid price requirement for continued listing on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450** ( ~~b~~ **a** ) ~~and 20~~ ( ~~a~~ **1** ) ~~of~~ **(** the **" Minimum Bid Price Requirement "). Nasdaq** ~~Exchange Act and Rule 10b- 5 promulgated thereunder on the basis of purportedly materially false and misleading statements and omissions concerning ADG20~~ ' s ~~effectiveness against~~ **notice had no immediate effect on** the **listing** ~~Omicron variant~~ of ~~COVID- 19~~ **our common stock, and, in accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we were provided an initial period of 180 calendar days, or until June 25, 2025, to regain compliance with the Minimum Bid Price Requirement by maintaining a closing bid price of at least $ 1** . ~~The complaint~~ **00 per share for a minimum of ten consecutive business days. On February 21, 2025, we received a letter from Nasdaq notifying us that we had regained compliance with the Minimum Bid Price Requirement, and the matter was closed. We actively monitor our stock price, and** , as ~~amended~~ **appropriate** , ~~seeks~~ **will consider implementing available options to maintain or** , ~~among~~ **if necessary, regain compliance with** ~~other~~ -- **the Minimum Bid Price Requirement** ~~things, unspecified damages, attorneys' fees, expert fees, and other costs~~ . ~~We believe~~ **There can be no assurance, however,** that we **will be able** ~~have strong defenses, and we intend~~ to **maintain** ~~vigorously defend against this action. However, whether~~ or ~~not the claim is successful~~ , ~~litigation is often expensive~~ **if necessary, regain compliance with the Minimum Bid Price Requirement** and **meet Nasdaq** ~~can divert management~~ ' s ~~attention and resources~~ **other continued listing requirements. To the extent that we are unable to maintain or, if necessary, regain compliance with the Minimum Bid Price Requirement or Nasdaq' s other continued listing requirements, there is a risk that our common stock may be delisted** from ~~other business concerns, which could~~ **Nasdaq. Delisting from Nasdaq may** adversely affect our **ability to raise** ~~business. We may be the target of similar litigation in the future. We previously identified a material weakness in our internal control over financial reporting, we may identify~~ additional **financing through** ~~material weaknesses in~~ the **public** ~~future that may cause us to fail to meet our~~ - **or private sale** ~~reporting obligations or result in material misstatements~~ of **equity securities** ~~our financial statements. If we fail to remediate any such weaknesses~~ , **significantly affect the** ~~or if we otherwise fail to establish and maintain effective control over financial reporting, our~~ ability **of investors** to ~~accurately and timely report~~ **trade our securities,** ~~our~~ - **or negatively** ~~financial results could be adversely affected, which may adversely~~ affect ~~our business. In connection with the preparation of our financial statements for the quarter ended March 31, 2021, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness identified related to a lack of effective controls over the completeness and accuracy of research and development expenses, prepaid expenses, accounts payable and accrued expenses related to our contract manufacturing agreements during interim financial reporting periods. This material weakness resulted in adjustments to research and development expenses for the three months ended March 31, 2021 and prepaid expenses, accounts payable and accrued expenses as of March 31, 2021, all of which were recorded prior to the issuance of our interim financial consolidated financial statements for that quarter. We subsequently designed and implemented controls to remediate the material weakness, including strengthening and formalizing our documentation of policies and further evolving our accounting processes and post- closing review procedures related to the completeness and accuracy of research and development expenses, prepaid expenses, accounts payable and accrued expenses of our contract manufacturing agreements, and our management concluded that we remediated the material weakness as of December 31, 2021. The process of designing and implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that satisfies our reporting obligations. If we are unable to meet the demands that have been placed upon us as a public company, including the requirements of the Sarbanes- Oxley Act of 2002 (the " Sarbanes- Oxley Act "), and we may be unable to accurately report our financial results, or report them~~ - **the value and liquidity of** ~~within the timeframes required by law or~~ **our common** stock ~~exchange regulations~~ . **Delisting** ~~Failure to comply with the Sarbanes- Oxley Act, when and as applicable, could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Furthermore, if we cannot provide reliable financial reports or prevent material misstatements due to fraud or error, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information. We~~ also could ~~become subject to investigations by The~~ **have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in potential business development opportunities. Furthermore, if we are delisted from** Nasdaq **and we are not able to list our common** ~~Stock~~ **stock on another exchange, our common stock may be eligible to trade on an over- the- counter system, such as the OTCQB** ~~Market~~ **market** ~~(~~ **(" , where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from** Nasdaq ~~")~~ , ~~the SEC or~~ **will be listed on** ~~other~~ **another national securities exchange** ~~regulatory authorities. All these possibilities could increase our~~ - **or** ~~operating costs~~ **quoted on** ~~and~~ - **an** ~~harm our business~~ **over- the- counter quotation system** . If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us

and our business. As a relatively new public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline. A significant portion of our total outstanding shares are available for immediate resale. This could cause the market price of our common stock to drop significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. We have filed registration statements on Form S- 8 under the Securities Act of 1933, as amended (the " Securities Act "), registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S- 8 will be available for sale in the public market subject to vesting arrangements and exercise of options and the restrictions of Rule 144 in the case of our affiliates. Additionally, several of our large stockholders, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. On February 9, 2024, we filed a registration statement on Form S- 3 to register an aggregate of up to 37, 745, 998 shares of our common stock held by holders with registration rights, including 30, 921, 286 issued and outstanding shares of our common stock and 6, 824, 712 shares of common stock issuable upon exercise of an outstanding common stock purchase warrant issued by us. ~~Once such~~ **Such** ~~Form S- 3 is declared effective by the SEC, such~~ shares of common stock may be freely sold in the public market for so long as such Form S- 3 remains effective, subject to the vesting and the exercise of the common stock purchase warrant with respect to the shares of common stock underlying such warrant. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result. There are provisions in our amended and restated certificate of incorporation and amended and restated bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10, 000, 000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders. Our charter documents also contain other provisions that could have an anti- takeover effect, including: • stockholders are not permitted to take actions by written consent; • stockholders cannot call a special meeting of stockholders; and • stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings. In addition, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law **(" DGCL ")** , which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions. Our executive officers, directors and current beneficial owners of five percent or more of our common stock and their respective affiliates beneficially own a majority of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions. Some of these persons or entities may have interests different than yours. For example, because many of these have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. We are an " emerging growth company, " and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors. We are an " emerging growth company, " within the meaning of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, as amended (the " JOBS Act "), and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of the IPO. However, if certain events occur prior to the end of such five- year period, including if we become a " large accelerated filer, " our annual gross revenues are $ 1. 235 billion or more or we issue more than $ 1. 0 billion of non- convertible debt in the previous three- year period, we will cease to be an emerging growth company prior to the end of such five- year period. For so long as we remain an emerging growth company, we are permitted and intend to take advantage of exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include: • an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting; • reduced disclosure obligations regarding executive compensation; • exemptions from the requirements of holding a non- binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved; and • an exemption from compliance with the requirements of the Public

Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor' s report on the financial statements. As a result, our shareholders may not have access to certain information they may deem important. We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result of our reliance on these exemptions, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We are a " smaller reporting company " and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are a " smaller reporting company " as defined in Item 10 (f) (1) of Regulation S- K, and will remain a smaller reporting company so long as either of the following conditions are true – (i) the market value of our common stock held by non- affiliates is less than $ 250 million as of the end of that year' s second fiscal quarter, or (ii) our annual revenues are less than $ 100 million during the most recently completed fiscal year and the market value of our common stock held by non- affiliates is less than $ 700 million as of the end of that year' s second fiscal quarter. We are therefore entitled to rely on certain reduced disclosure requirements for as long as we remain a smaller reporting company, such as an exemption from providing selected financial data and certain executive compensation information. In addition, for as long as we are a smaller reporting company with less than $ 100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404 of the Sarbanes- Oxley Act. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile. ~~We have broad discretion in the use of our cash, cash equivalents and marketable securities, as applicable, including the net proceeds from our IPO and any sales of our common stock made under our Sales Agreement with Cantor. We have broad discretion over the use of our cash, cash equivalents and marketable securities, as applicable, including the net proceeds from our IPO and any sales of our common stock made under Sales Agreement with Cantor. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply our cash, cash equivalents and marketable securities effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of our cash, cash equivalents and marketable securities. You will not have the opportunity to influence our decisions on how to use our cash, cash equivalents and marketable securities.~~ Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment. You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the U. S. of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: • any derivative action or proceeding brought on our behalf; • any action asserting a breach of fiduciary duty; • any action asserting a claim against us arising under the ~~Delaware General Corporation Law (the "~~ DGCL ~~")~~, our amended and restated certificate of incorporation, or our amended and restated bylaws; • any action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; • any action to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and • any action asserting a claim against us that is governed by the internal- affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the ~~United States of America~~ **U. S.** will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations and prospects. These exclusive forum provisions may result in increased costs for investors to bring a claim. Further, these exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our

directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive- forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business. General Risk Factors ~~We have incurred and will continue to incur increased costs and demands upon management as a result of becoming a public company, which could lower our profits or make it more difficult to run our business. As a public company, we have incurred and, particularly after we are no longer an emerging growth company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes- Oxley Act, and related rules implemented by the SEC and Nasdaq. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time- consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees, or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation. We and certain of our former officers have been named as defendants in a pending securities class action lawsuit. This lawsuit, and potential similar or related lawsuits or investigations, could result in substantial damages, divert management' s time and attention from our business, and have a material adverse effect on our results of operations. This lawsuit, and any other lawsuits or investigations to which we are subject, will be costly to defend or comply with and are uncertain in their outcome. On January 31, 2023, a securities class action lawsuit captioned Brill v. Invivyd, Inc., et. al., Case No. 1: 23- CV- 10254- LTS, was filed against us and certain of our former officers in the U. S. District Court for the District of Massachusetts. The complaint, as amended, alleges violations of Sections 10 (b) and 20 (a) of the Exchange Act and Rule 10b- 5 promulgated thereunder on the basis of purportedly materially false and misleading statements and omissions concerning ADG20' s effectiveness against the Omicron variant of COVID- 19. The complaint, as amended, seeks, among other things, unspecified damages, attorneys' fees, expert fees, and other costs. We currently are not able to estimate the possible cost to us from this action, as the pending lawsuit is currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuit or the possible amount of any damages that we may be required to pay. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations. Additionally, we received a request from the SEC, dated March 22, 2023, for documents and information concerning, among other matters, our testing and analysis of the efficacy of ADG20 against Omicron and other COVID- 19 variants, our public statements regarding the potential use of ADG20 against the Omicron variant, and related communications with investors and the media. By letter dated August 9, 2023, the SEC notified us that the SEC had concluded its investigation and did not intend to recommend any action against us. We may be the target of similar litigation or investigations in the future. The market price of our common stock has experienced and may continue to experience volatility, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation. Any future litigation or investigation could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. We maintain liability insurance; however, if any costs or expenses associated with pending lawsuits or any other litigation or investigation exceed our insurance coverage, we may be forced to bear some or all costs and expenses directly, which could adversely affect our business, financial condition, results of operations or stock price.~~ Our ability to use net operating losses to offset future taxable income may be subject to certain limitations ~~. We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever~~ . To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. As of December 31, ~~2023~~ **2024** , we had U. S. federal net operating loss (" NOL ") carryforwards of $ ~~318~~ **392** . ~~6~~ **0** million, which may be available to reduce future taxable income and have an indefinite carryforward period but are limited in their usage to an annual deduction equal to 80 % of annual taxable income. In addition, as of December 31, ~~2023~~ **2024** , we had state NOL carryforwards of $ ~~153~~ **249** . ~~8~~ **3** million, which may be available to reduce future taxable income, of which $ ~~9~~ **24** . ~~6~~ **3** million have an indefinite carryforward period while the remaining $ ~~144~~ **225** . ~~2~~ **0** million begin to expire in 2032. As of December 31, ~~2023~~ **2024** , we also had U. S. federal and state research and development tax credit carryforwards of $ ~~19~~ **23** . ~~3~~ **0** million and $ ~~6~~ **7** . ~~4~~ **2** million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in ~~2041~~ **2040** and ~~2036~~ **2035** respectively. Under the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act (the " CARES Act "), federal NOLs incurred in taxable years beginning after December 31, 2017 and in future taxable years may carry forward indefinitely, but the deductibility of such federal NOLs incurred in taxable years beginning after December 31, 2020 may be limited. There is variation in how states are responding. In addition, for state income tax purposes, there may be periods during which the use of NOLs is suspended or otherwise limited. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. The IPO, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced, and may in the future experience, ownership changes as a result of shifts in our stock ownership, some of which may be outside of our control. If an ownership

change has occurred or occurs in the future, and our ability to use our NOL carryforwards is materially limited, it would harm our financial condition and results of operations by effectively increasing our future tax obligations. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. Beginning in 2022, the Tax Act now eliminates the previously available option to deduct research and development expenditures and requires taxpayers to amortize them over five or fifteen years. Although U. S. Congress considered legislation that would defer the amortization requirement to future periods; the provision has not been repealed or otherwise modified. We maintain our cash at financial institutions, often in balances that exceed federally insured limits. The majority of our cash is held in accounts at U. S. banking institutions that we believe are of high quality. Cash held in depository accounts may exceed the $ 250, 000 Federal Deposit Insurance Corporation (" FDIC ") insurance limits. If such banking institutions were to fail, such as Silicon Valley Bank when the FDIC took control in March 2023, we could lose all or a portion of those amounts held in excess of such insurance limitations. In the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. Any material loss that we may experience in the future could have a material adverse effect on our financial condition and could materially impact our ability to pay our operational expenses or make other payments. Our business activities are subject to the FCPA and similar anti- bribery and anti- corruption laws. We could face liability and other serious consequences for violations. We are subject to anti- corruption laws and regulations, including 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- U. S. 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- U. S. governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently 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, manufacturer, 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 manufacturer, 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. Disruptions at the FDA, the SEC and other government agencies caused by **the U. S. presidential administration,** funding shortages or global health concerns 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 ability of the FDA to review and approve new products **or review other regulatory submissions** can be affected by a variety of factors, including government budget and funding levels, **a reduction in the FDA' s workforce and its** ability to hire and retain key personnel and accept the payment of user fees **, shifting policy priorities as a result of changes in the U. S. presidential administration and political appointees tasked to oversee the agency** , and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. 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. Disruptions at the FDA and other agencies may also ~~slow~~ **increase** the time ~~necessary for new drugs or biologics~~ to ~~be~~ **meet with and receive agency feedback,** ~~reviewed~~ -- **review** and / or ~~approved~~ - **approve** ~~by necessary government agencies~~ **our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products** , which would adversely affect our business. **In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies.** For example, over the last several years ~~, including most recently from December 22, 2018 to January 25, 2019~~ , the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. **Further, the current U. S. presidential administration recently established the Department of Government Efficiency, which implemented a federal government hiring freeze and announced certain additional efforts to reduce federal government employee headcount and the size of the federal government. It is unclear how these executive actions or other potential actions by the current U. S. presidential administration or other parts of the federal government will impact the FDA or other regulatory authorities that oversee our business. These budgetary pressures may reduce the FDA' s ability to perform its responsibilities.** If a ~~prolonged government shutdown~~ **significant reduction in the FDA' s workforce** occurs, ~~it could~~ **the FDA' s budget is** significantly **reduced** ~~impact the ability of the FDA to timely review and process our~~ - **or** ~~regulatory submissions, which could have a material adverse effect on our business. Separately, in response to the COVID- 19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of~~

~~foreign manufacturing facilities and products and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Since then, the FDA has resumed both domestic and foreign inspections subject to travel restrictions. If~~ a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions **or take other actions critical to the development or marketing of our product candidates** , which could have a material adverse effect on our business. Unfavorable global economic conditions and geopolitical events **, including as a result of trade tensions between the U. S. and China,** could adversely affect our business, financial condition or results of operations, including **conduct of our** clinical trials **and our manufacturing activities** . Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine, terrorism or other ~~geopolitical~~ --- **political** events, including as a result of trade tensions between the U. S. and China. Sanctions imposed by the U. S. and other countries in response to conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. We have conducted and may in the future conduct clinical trials for our product candidates outside of the U. S. and unfavorable economic conditions resulting in the weakening of the U. S. dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, ~~including a recession or depression resulting from the COVID- 19 pandemic,~~ higher inflation and interest rates, political disruption or other geopolitical events, including an expansion of the conflict between Russia and Ukraine or instigation of other military conflicts, could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if authorized or approved, and our ability to raise additional capital when needed on acceptable terms, if at all. **Additionally, political pressures, shifting public health priorities, and evolving FDA policies under the new U. S. presidential administration could also impact the demand for COVID- 19- related prevention and treatment measures, affecting the commercial potential of our COVID- 19 product candidates.** A weak or declining economy or political disruption, including any international trade disputes **,** or changes in **laws or policies governing the terms of international trade, and in particular increased trade restrictions, tariffs or taxes on imports from countries where we manufacture products, such as China, could strain our manufacturer or suppliers, possibly resulting in supply disruption or increased manufacturing and distribution costs. For example, in 2025, the** U. S. **imposed tariffs on certain imports from Canada, Mexico and China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U. S. goods. Political tensions as a result of** trade policies ~~, particularly with China,~~ could **reduce trade volume** ~~also strain our manufacturer or suppliers~~ , ~~possibly~~ **investment, technological exchange and other economic activities between major international economies,** resulting in ~~supply disruption, or cause our customers to delay making payments for our potential products~~ **a material adverse effect on global economic conditions and the stability of global financial markets** . Furthermore, while we seek to limit our concentration of risk as it relates to cash management by having a separate operating bank account with a U. S. commercial bank for routine disbursements, while maintaining our cash investments with an independent SEC- registered financial advisor, our liquidity, business and financial condition may be materially and adversely affected by unanticipated events such as a bank collapse. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business. ~~97~~