Risk Factors Comparison 2025-02-20 to 2024-02-22 Form: 10-K

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An investment in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, in addition to the other information contained in this Annual Report on Form 10- K, including our consolidated financial statements and related notes, before making an investment decision. The risks described below are not the only ones facing us. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Annual Report on Form 10- K also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10- K. Risks Related to our Business and Capital Requirements HEPLISAV- B has been approved in the United States, the European Union and ~~Great Britain~~ **the United Kingdom** and launched in the United States and Germany, and there is significant competition in these marketplaces. Since this is our first marketed product, the timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for HEPLISAV- B. We have established sales, marketing and distribution capabilities and commercialized HEPLISAV- B in the United States and Germany. We have also received approval in the European Union and ~~Great Britain~~ **the United Kingdom** for HEPLISAV- B. Successful commercialization of HEPLISAV- B in these regions or elsewhere will require significant resources and time, and there can be no certainty that we will succeed in these efforts. While our personnel are experienced with respect to marketing of healthcare products, because HEPLISAV- B is our first marketed product, the potential uptake of the product through distribution, and the timing, trajectory, rate and sustainability for growth in sales is unpredictable, and we may not be successful in commercializing HEPLISAV- B in the long term. In particular, successful commercialization of HEPLISAV- B will require that we continue to negotiate and enter into contracts with wholesalers, distributors, group purchasing organizations, and other parties, and that we maintain those contractual relationships. There is a risk that we may fail to complete or maintain some or all of these important contracts on favorable terms or at all, or that in a potentially evolving reimbursement environment, our efforts may fail to overcome established competition at favorable pricing, or at all. We have continued to expand our field sales force. As these teams expand, it will take time for our expanded teams to generate significant sales momentum, if they do so at all. Although we have had some success growing and developing our field sales force following the launch of HEPLISAV- B, there is no guarantee that we will be able to generate sales at the same or improved rates going forward, if at all. In addition, retention of capable sales personnel may be more difficult for us compared to our competitors, as we focus on a single product offering. We must retain our sales force in order for HEPLISAV- B to maintain or expand its commercial presence. Moreover, we expect that we will need to divert resources in order to successfully market, sell and distribute HEPLISAV- B for use with dialysis patients, one of our targeted patient populations. We do not yet have approval to market the regimen for dialysis **. In the second quarter of 2024, the FDA issued a Complete Response Letter (" CRL ") for the supplemental Biologics License Application (" sBLA ") to include a four- dose regimen for adults on hemodialysis in the U. S. label, and we are exploring approaches to address the deficiencies noted in the CRL. In the fourth quarter of 2024, we received feedback from the FDA regarding the potential to conduct an observational retrospective cohort study to support our sBLA filing for adults on hemodialysis. We expect to resubmit our sBLA for HEPLISAV- B vaccination of adults on hemodialysis to the FDA in 2025. We may be unsuccessful in conducting an observational retrospective cohort study, may not successfully resubmit our sBLA for a four- dose regimen for adults on hemodialysis, and may never obtain FDA approval for such indication, which would limit our addressable market and revenue** . Although the Centers for Disease Control and Prevention (" CDC ") and the CDC' s Advisory Committee on Immunization Practices (" ACIP ") recommend that all adults aged 19- 59, including patients on dialysis, receive hepatitis B vaccinations, our predictions of how many of those patients actually receive HEPLISAV- B may be inaccurate. In **particular, vaccine skepticism and disinformation may impact the willingness of patients to consider hepatitis B vaccination. In** addition to the risks with employing and maintaining our own commercial capabilities and with contracting, other factors that may inhibit our efforts to successfully commercialize HEPLISAV- B include: • whether we are able to continue recruiting and retaining adequate numbers of effective sales and marketing personnel; • whether we are able to access key health care providers to discuss HEPLISAV- B; • whether we can continue to compete successfully as a relatively new entrant in established distribution channels for vaccine products; and • whether we will maintain sufficient financial resources to cover the costs and expenses associated with sustaining a capable sales and marketing organization and related commercial infrastructure. If we are not able to enter new markets ourselves, we may be required to collaborate or partner HEPLISAV- B with a third- party pharmaceutical or biotechnology company with existing products. To the extent we collaborate or partner, as we have done for HEPLISAV- B distribution in Germany, the product' s financial value will be shared with another party and we will need to establish and maintain a successful collaboration arrangement, and we may not be able to enter into these arrangements on acceptable terms or in a timely manner in order to establish HEPLISAV- B in these new markets. To the extent that we enter into co- promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In that event, our product revenues may be lower than if we marketed and sold our products directly with the highest priority, and we may be required to reduce or eliminate much of our commercial infrastructure and personnel as a result of such collaboration or partnership. Governments influence the price of medicinal products in the European Union through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Even though we have been granted

a marketing authorization in the European Union for HEPLISAV- B, we have yet to obtain broad reimbursements and pricing approval in any European Union Member State and rely on our distributor to do so, who currently only markets in Germany. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost- effectiveness of a particular product candidate to currently available therapies. Other European Union Member States allow companies to fix their own prices for medicines, but monitor and control company profits. Any delay in being able to market our products in the European Union, ~~Great Britain~~ **the United Kingdom** or elsewhere may adversely affect our business and financial condition. If we, or our partners, are not successful in setting our marketing, pricing and reimbursement strategies, recruiting and maintaining effective sales and marketing personnel or building and maintaining the infrastructure to support commercial operations in the U. S., Germany and elsewhere, we will have difficulty successfully commercializing HEPLISAV- B, which would adversely affect our business and financial condition. Our financial results may vary significantly from quarter to quarter or may fall below the expectations of investors or securities analysts, each of which may adversely affect our stock price. Numerous factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. For example, during the year ended December 31, 2022, we recognized $ 587. 7 million of CpG 1018 adjuvant revenue. However, our CpG 1018 adjuvant supply agreements expired at the end of 2022, and as a result, we did not recognize CpG 1018 adjuvant revenue for the ~~year~~ **years** ended **December 31, 2024 and** December 31, 2023. Similarly, if demand for HEPLISAV- B decreases from recent trends for any reason, that could also cause unexpected fluctuations in our quarterly and annual operating results. The occurrence and timing of any transfer of control of product sold to customers can also be difficult to predict, and the recognition of revenue can vary widely depending on timing of product deliveries and satisfaction of other obligations. As an example, any future revenue we do receive from sales of our CpG 1018 adjuvant has been and will continue to be difficult to predict, if it materializes at all. Historically, we generally required customers to place orders for CpG 1018 adjuvant with at least six months lead time and to make an advance payment toward the finished order. Where we receive such advance payments, we record such payments as deferred revenue until we have delivered the adjuvant and met all criteria to recognize revenue. In accordance with our stated revenue policy, we historically recorded revenue for these contracts upon meeting all of the criteria for revenue recognition under Accounting Standards Codification 606, which includes, among other criteria, the transfer of control for CpG 1018 adjuvant to our customer. During the year ended December 31, **2024 and December 31,** 2023, we did not receive any advanced payments from any of our customers to purchase CpG 1018 adjuvant. Our collaborators in many cases have purchase agreements with government agencies. If our collaborators do not receive payment from these agencies for any past or future adjuvant orders, our ability to collect our own receivables may be adversely affected. For example, as of December 31, 2023, we had recorded an allowance for doubtful accounts of $ 12. 3 million in connection with our accounts receivable balance due from Bio E, which was determined by assessing changes in Bio E' s credit risk, contemplation of ongoing negotiations relating to an amendment to the supply agreement with Bio E, and Bio E' s dependence on cash collections from the Government of India, which have been delayed significantly by the Government of India. We have in the past, and may in the future, adjust delivery dates, allow cancellations or give concessions on outstanding receivables in certain circumstances to better enable our customers to meet their obligations, which can impact the timing or amount of our revenue recognition, cash collections and transfer of control. For example, in August and October 2022, we entered into amendments to our Supply Agreement, dated June 29, 2021, with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited (the" Clover Supply Agreement"), which, among other things, modified the scope of the Clover Supply Agreement to reduce certain quantities of CpG 1018 adjuvant deliverable under the agreement and / or reduce amounts receivable, which we originally intended to deliver in accordance with a purchase order previously issued by Clover, and apply prepayments Clover previously made to us as payment for portions of pending outstanding purchase orders. In January 2023, we entered into another amendment to the Clover Supply Agreement to modify the price per dose of CpG 1018 adjuvant paid by Clover for adjuvant used in finished vaccine doses sold through government procurement programs relating to the booster program promoted by the China National Health Commission. In addition, in April 2023, we entered into the Bio E Amendment No. 3 and the CEPI- Bio E Assignment Agreement, pursuant to which CEPI forgave amounts outstanding relating to the Bio E CEPI Advance Payments and assumed our previous rights to collect $ 47. 4 million of Bio E accounts receivable. Among other things, the CEPI- Bio E Assignment Agreement resulted in no accounts receivable from Bio E, the derecognition of $ 47. 4 million CEPI accrual in connection with the Bio E CEPI Advance Payments, and certain additional future payments contingent on Bio E' s receipt of payments from the Government of India associated with its CORBEVAX product on or before August 15, 2025, which may not materialize. Moreover, our revenue or operating expenses in one period may be disproportionately higher or lower relative to the others due to, among other factors, revenue fluctuations or increases in expenses as we invest in our pipeline **. We may also incur significant expenses in any given reporting period related to shareholder engagement matters, including, without limitation, fees for legal, financial and other professional advisors** . Accordingly, comparing our operating results on a period- to- period basis may not be meaningful, and investors should not rely on any particular past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of investors or securities analysts, our stock price may be adversely affected. We have incurred annual net losses in most years since our inception and could continue to incur significant losses if we do not successfully commercialize HEPLISAV- B, launch new products and / or significant sales of our CpG 1018 adjuvant do not resume. Prior to January 1, 2021, we had incurred losses in each year since we commenced operations in 1996. ~~We~~ **While we recognized revenue for the years ended December 31, 2021, 2022 and 2024, we** recognized a net loss of $ 6. 4 million for the year ended December 31, 2023. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~930~~ **903** . ~~6~~ **3** million. With our investment in the launch and commercialization of HEPLISAV- B in the United States and Germany, we have in the past, and could in the future, incur

operating losses. Our expenses have increased substantially as we maintain our HEPLISAV- B commercial infrastructure, including investments in internal infrastructure to support our field sales force and investments in manufacturing and supply chain commitments to maintain commercial supply of HEPLISAV- B. Further, we expect to increase research and development costs as we invest in our pipeline. We are already advancing a multi- program clinical pipeline leveraging CpG 1018 adjuvant to develop improved vaccines in indications with unmet medical needs including **a** Phase 1 **/ 2** clinical ~~trials~~ **trial** ~~in~~ **for** shingles and ~~Tdap,~~ **additional clinical** and **manufacturing activities, including** a Phase 2 clinical trial **expected to initiate in the third quarter of 2025,** for plague in collaboration with and fully funded by the U. S. Department of Defense (" DoD "). We expect research and development costs to increase further if we add additional programs to our pipeline. Sales of CpG 1018 adjuvant generated significant revenue during the COVID- 19 pandemic, but we do not **currently** expect such revenues to continue in the long term, and we did not recognize any CpG 1018 adjuvant revenue in the year ended December 31, 2023 **nor December 31, 2024** . The timing for uptake of our products in the U. S. and abroad may further affect costs or losses related to commercialization. Due to the numerous risks and uncertainties associated with developing and commercializing vaccine products or other products we may choose to offer in the future, we are unable to predict the extent of any future losses or when, if ever, we will become profitable on an annual recurring basis, or, that if we are able to reach consistent profitability that it will be sustainable for any period of time. Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors as a result of these disadvantages, we may be unable to generate sufficient, or any, revenues and our business will be harmed. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing and marketing vaccines and adjuvants. For example, HEPLISAV- B competes in the U. S. with established hepatitis B vaccines marketed by Merck, GlaxoSmithKline plc (" GSK ") and VBI Vaccines Inc. (" VBI"), and with vaccines from those companies as well as several additional established pharmaceutical companies who market abroad. There are also modified schedules of conventional hepatitis B vaccines for limited age ranges that are approved in the United States, the European Union and ~~Great Britain~~ **the United Kingdom** . Competition in European markets could affect our success or the success of our distributor in that market as well. In addition, HEPLISAV- B competes against Twinrix, a bivalent vaccine marketed by GSK for protection against hepatitis B and hepatitis A. We are also in competition with companies developing vaccines and vaccine adjuvants, generally including, among others, GSK, Pfizer, Inc., Sanofi S. A., Merck, Bavarian Nordic A / S, Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva, AstraZeneca plc, Moderna, Inc., Johnson & Johnson, VBI, BioNTech SE and Curevo Vaccine. We will likely compete with several of these companies in the hepatitis space, shingles space, ~~Tdap space~~ and other spaces occupied by any other product candidates we ultimately choose to advance through our pipeline in the future. Products in our clinical pipeline, if approved, will also face competition from competitors who have competing clinical programs or already approved products. Existing and potential competitors or other market participants may also compete with us for qualified commercial, scientific and management personnel, as well as for technology that would otherwise be advantageous to our business. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified personnel in the near- term, particularly with respect to HEPLISAV- B commercialization. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to properly manage our business, obtain financing as needed, enter into collaborative arrangements, advance or sell our product candidates or generate revenues. We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture our products and our product candidates. We rely on a limited number of suppliers to produce the oligonucleotides we require for development and commercialization. Additionally, we have limited experience in manufacturing our products or product candidates in commercial quantities. With respect to HEPLISAV- B, we use a pre- filled syringe presentation of the vaccine and our ability to meet future demand will depend on our ability to manufacture or have manufactured sufficient supply in this presentation. We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing hepatitis B surface antigen for use in HEPLISAV- B, the combination of the oligonucleotide and the antigens, and formulation, fill and finish. We may continue to do the same for any additional products we might add in the future through natural internal expansion of our pipeline, or in transactions with an external third- party or parties. The FDA approved our pre- filled syringe presentation of HEPLISAV- B in 2018 and we expect such presentation will be the sole presentation for HEPLISAV- B going forward. We have limited experience in manufacturing and supplying this presentation ourselves, and rely on a contract manufacturer to do so. Our contract manufacturer is the only approved provider that we have, and there can be no assurance that we or they can successfully manufacture sufficient quantities of pre- filled syringes in compliance with good manufacturing practice (" GMP") in order to meet market demand, whether because of problems with our supplier' s own operations, operations of its sub- suppliers, issues with downstream supply chains or otherwise. If our contract manufacturer is unable to source components needed to complete fill and finish of our pre- filled syringes, we may be required to identify a second source which would have associated costs and regulatory requirements. Qualifying a second source could take more than a year to accomplish. If we are unable to do all this, on a timely basis or at all, our HEPLISAV- B sales could be materially and adversely impacted. Historically, we have also relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce (i) our CpG 1018 adjuvant for manufacture of HEPLISAV- B and for sale to our collaborators and (ii) our pre- filled syringe presentation. In 2021, we qualified a second supplier to manufacture CpG 1018 adjuvant for our COVID business. If we are unable to maintain our existing suppliers for CpG 1018 adjuvant, we would have to establish an alternate qualified manufacturing capability ourselves, which would result in significant additional operating costs and delays in manufacturing HEPLISAV- B, or CpG 1018 adjuvant, and developing and commercializing our, and potentially our collaborators', product candidates. We or other third parties may not be able to produce product at a cost, quantity and quality that are available from our current third- party suppliers, or at all. In countries outside of the U. S., we may not be able to comply with comparable foreign regulations, and our manufacturing

process may be subject to delays, disruptions or quality control / quality assurance problems. Noncompliance with these regulations or other problems with our manufacturing process may limit or disrupt the commercialization of our products or our and our collaborators' product candidates and could result in significant expense. As we continue to focus on the commercialization of our HEPLISAV- B vaccine and our CpG 1018 adjuvant, we may encounter difficulties in managing our commercial growth and expanding our operations successfully. As our commercial operations expand, we expect that we will also need to manage additional relationships with various third parties, including sole source suppliers, distributors, collaboration partners, wholesalers and hospital customers. Future growth will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to successfully commercialize our HEPLISAV- B vaccine and CpG 1018 adjuvant or any new products, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we may not be able to manage our growth efforts effectively, and hire, train, retain and integrate additional management, administrative and sales and marketing personnel, or secure sufficient or timely supply from third party service and product providers. Any failure to accomplish any of these activities could prevent us from successfully increasing or maintaining the same level of commercial growth as we have seen in the past. If HEPLISAV- B or any products we develop are not accepted by the market or if regulatory authorities limit our labeling indications, require labeling content that diminishes market uptake of HEPLISAV- B or any other products we develop, or limit our marketing claims, we may be unable to generate significant future revenues, if any. Even if we obtain regulatory approval for our product candidates, such as our U. S., European Union and ~~Great Britain~~ **the United Kingdom** approvals of HEPLISAV- B, and are able to commercialize them as we have with HEPLISAV- B, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of HEPLISAV- B and any of our future approved products will depend upon a number of factors, including: • the indication for which the product is approved and its approved labeling; • the presence of other competing approved products; • the potential advantages of the product over existing and future treatment methods; • the relative convenience and ease of administration of the product; • the strength of our sales, marketing and distribution efforts; • the price and cost- effectiveness of the product; and • third- party coverage and adequate reimbursement and the willingness of patients to pay out- of- pocket in the absence of sufficient reimbursement by third- party payors. **Market acceptance of vaccines has been negatively impacted in recent years due to increasing vaccine skepticism and disinformation. The potential for individuals with anti- vaccine views to hold governmental and other roles of influence and for disinformation campaigns to negatively impact potential market acceptance for HEPLISAV- B and any of our future approved products may slow our sales growth and weaken our market prospects.** The FDA or other regulatory authorities could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to achieve approval or successfully market any of our products or product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenue could be significantly impaired. As we continue to grow as a commercial organization and enter into supply agreements with customers, those supply agreements will have obligations to deliver product that we are **in part** reliant upon third parties to manufacture on our behalf. As our commercial business begins to expand in connection with commercial sales of HEPLISAV- B or CpG 1018 adjuvant, as applicable, the contracts we enter into with our customers will generally carry delivery obligations that require us to deliver product in certain quantities and meet certain quality thresholds, among other things, all within specified timeframes. If, for any reason, whether due to reliance on third- party manufacturers or otherwise, we are unable to deliver timely, compliant products to our customers in quantities that meet our contractual obligations, we could be subject to lost revenue, contractual penalties, suits for damages, harm to our reputation or other problems that could materially and adversely affect our business. To the extent we add new products in the future, these risks could be exacerbated by the added complexity of managing multiple product lines. We face uncertainty regarding coverage, pricing and reimbursement and the practices of third- party payors, which may make it difficult or impossible to sell certain of our products or product candidates on commercially reasonable terms. In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price, as well as the availability of coverage and adequate reimbursement, from third- party payors, in particular for HEPLISAV- B, where existing products are already marketed. In the U. S., pricing for hepatitis B vaccines is currently stable and reimbursement is favorable as we believe private and public payors recognize the value of prophylaxis in this setting given the high costs of potential morbidity and mortality, and we have achieved coverage with most third- party payors. However, there is a risk that some payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include HEPLISAV- B. Reimbursement or pricing in jurisdictions outside the U. S. may be less favorable. Thus, there can be no assurance that HEPLISAV- B will achieve and sustain stable pricing and favorable reimbursement. ~~Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.~~ Our ability to successfully obtain and retain market share and achieve and sustain profitability will be significantly dependent on the market' s acceptance of a price for HEPLISAV- B sufficient to achieve profitability, and future acceptance of such pricing. Third- party payors are increasingly challenging the price and cost- effectiveness of medical products and services, and pricing, as well as coverage and reimbursement decisions, may not allow our future products to compete effectively with existing competitive products. Because we intend to offer products, if approved, that involve new technologies, the willingness of third- party payors to reimburse for our products is uncertain. We will have to charge a price for HEPLISAV- B or any other products we commercialize that is sufficient to enable us to recover our considerable investment in product development and our operating costs. Further, coverage policies and third - party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. **For example, the newly elected Presidential administration may be more skeptical of the safety and efficacy of vaccine products, which could lead to increased regulatory scrutiny and more restrictive coverage policies regarding our**

products and product candidates. Adequate third- party payor reimbursement may not be available to enable us to maintain price levels sufficient to achieve or maintain profitability, and such unavailability could harm our future prospects and reduce our stock price. The ~~United Kingdom (" UK ")~~ and many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in European countries 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 our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. This Health Technology Assessment (" HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process 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 EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021 / 2282 on HTA amending Directive 2011 / 24 / EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and **applies** ~~will apply~~ as of January **12,** 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation ~~foresees a three- year transitional period and will permit~~ **permits** EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States ~~will~~ continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the **UK** ~~United Kingdom~~ has left the EU, Regulation No 2021 / 2282 on HTA ~~will~~ **does** not apply in the **UK** ~~United Kingdom~~. However, the UK Medicines and Healthcare products Regulation Agency (" MHRA ") is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium (" SMC "), the National Institute for Health and Care Excellence (" NICE "), and the All- Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products. For example, in March 2021, the UK introduced the Innovative Licensing and Access ~~Pathways~~ **Pathway** (" ILAP ") which brings together the MHRA, NICE, SMC and the All Wales Therapeutics and Toxicology Centre, to accelerate time to market for certain innovative products. **The ILAP temporarily stopped accepting applications on November 20, 2024, but applications under a relaunched ILAP will reopen in March 2025, with changes including improvements to interaction with the National Health Service and an amended eligibility and selection criteria.** Legislators, policymakers and healthcare insurance funds in the EU and the **UK** ~~United Kingdom~~ may continue to propose and implement cost- containing measures to keep healthcare costs down, particularly due to the financial strain that COVID- 19 placed on national healthcare systems of European countries. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third- party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as " reference prices " to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. We are subject to ongoing FDA, EU and comparable foreign post- marketing obligations concerning HEPLISAV- B, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated regulatory issues with HEPLISAV- B. Our HEPLISAV- B regulatory approval in the United States is subject to certain post- marketing obligations and commitments to the FDA. For example, we were required to conduct an observational comparative study of HEPLISAV- B to Engerix- B to assess occurrence of acute myocardial infarction (" AMI "). This post- marketing study was initiated in August 2018 and concluded in November 2020. While the results of the study, announced in April 2021, indicated that there was no increased risk of AMI associated with vaccination with HEPLISAV- B compared to Engerix- B, we may be required to conduct further studies on HEPLISAV- B or our other product candidates in the future. Also, we received data from the autoimmune portion of our observational study, and the data indicated no association between HEPLISAV- B and any of the studied autoimmune diseases. In addition, we conducted a pregnancy registry study to provide information on outcomes following pregnancy exposure to HEPLISAV- B and submitted the information to the FDA in December 2023. **In May 2024, the FDA released us from the post- marketing commitment related to the pregnancy registry study.** Failure to complete ~~the study~~ **any future post- marketing obligation** to the satisfaction of the FDA could result in withdrawal of our biologics license application approval, which would have a material adverse effect on our business, results of operations, financial condition and prospects. As we advance our pipeline, similar studies may be required for other candidates. The results of post- marketing studies may also result in additional warnings or precautions for the HEPLISAV- B label or labels of any future products, if authorized, or expose additional safety concerns that may result in product liability and withdrawal of a product or products from the market, any of which would have a material adverse effect on our business, results of operations,

financial condition and prospects. Similar post- marketing obligations and commitments exist in the European Union and ~~Great Britain~~ **the UK** . For example, we are required to submit periodic safety update reports to the European Medicines Agency (" EMA") and the MHRA and to keep an up- to- date risk management plan that takes into account new information that may lead to a significant change in the risk / benefit profile of HEPLISAV- B. In addition, in accordance with our EU marketing authorization for HEPLISAV- B, HEPLISAV- B is subject to additional monitoring, meaning that it is monitored more intensively than other medicinal products. We may have similar obligations for future products if and when approved. Non-compliance with European Union or **UK** ~~United Kingdom~~ requirements regarding safety monitoring or pharmacovigilance can result in significant financial penalties. In addition, the manufacturing processes, labelling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for HEPLISAV- B are subject to extensive and ongoing regulatory requirements in the United States, the European Union and ~~Great Britain~~ **the UK** . These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with current good manufacturing practices (“ cGMP ”), good clinical practices (“ GCP ”), International Conference on Harmonization guidelines, and good laboratory practices (“ GLP ”). If we are not able to meet and maintain regulatory compliance for HEPLISAV- B or any future product, if authorized, we may lose marketing approval and be required to withdraw our product. Withdrawal of our product would have a material adverse effect on our business. HEPLISAV- B and all of our clinical programs rely on oligonucleotide TLR agonists. In the event of serious adverse events relating to TLR agonists, we may be required to reduce the scope of, or discontinue, our operations, or reevaluate the viability of strategic alternatives. Our programs, including HEPLISAV- B, incorporate TLR9 agonist CpG oligonucleotides. If any of our product candidates in clinical trials or similar products from competitors or collaborators result in serious adverse events, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy, or significantly reevaluate strategic alternatives. If a safety risk based on mechanism of action or the molecular structure were identified, it may hinder our ability to develop our product candidates or enter into potential collaboration or commercial arrangements. Rare diseases and a numerical imbalance in cardiac adverse events have been observed in patients in our clinical trials. If adverse events are found to relate to our TLR agonist as a whole, we may be required to significantly reduce or discontinue our operations. HEPLISAV- B is subject to regulatory obligations and continued regulatory review, and if we receive regulatory approval for our other product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review for such products. With respect to HEPLISAV- B and our other product candidates in development, we and our third- party manufacturers and suppliers are required to comply with applicable cGMP regulations and other international regulatory requirements. The regulations require that our products and product candidates be manufactured and records maintained in a prescribed manner with respect to manufacturing, testing and quality control / quality assurance activities. Manufacturers and suppliers of key components and materials must be named in a Biologics License Application (“ BLA ”) submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, third- party manufacturers and suppliers and any manufacturing facility must undergo a pre- approval inspection before we can obtain marketing authorization for any of our product candidates. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products or product candidates, our ability to control third- party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. If, as a result of the FDA’ s inspections, it determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may not approve the product or may suspend the manufacturing operations. If the manufacturing operations of any of the suppliers for our products or product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers is interrupted for any reason, we might be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant and costly delays can occur if the qualification of a new supplier is required. Similar requirements and procedures apply outside of the United States. Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and to our stock price. Regulatory authorities may require more clinical trials for our product candidates than we currently expect or are conducting before granting regulatory approval, if regulatory approval is granted at all. Our clinical trials may be extended which may lead to substantial delays in the regulatory approval process for our product candidates and may impair our ability to generate revenues. Our registration and commercial timelines depend on further discussions with regulatory authorities and requirements and any requests that they may make for additional data or completion of additional clinical trials. Any such requirements or requests could: • adversely affect our ability to timely and successfully commercialize or market these product candidates; • result in significant additional costs; • potentially diminish any competitive advantages for those products; • potentially limit the markets for those products; • adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators; • cause us to abandon the development of the affected product candidate; or • limit our ability to obtain additional financing on acceptable terms, if at all. Clinical trials for our commercial product and product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and have uncertain outcomes. Clinical trials, including post- marketing studies, to generate sufficient data to meet FDA and other regulatory authority requirements are expensive and time consuming, may take more time to complete than expected, may not be completed at all, and may not have favorable outcomes if they are completed. In addition, results from smaller, earlier stage clinical studies may

not be representative of larger, controlled clinical trials that would be required in order to obtain regulatory approval of a product candidate. Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain Institutional Review Board (" IRB "), Ethics Committee or regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available vaccine or component supply. Participant enrollment is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. Failure of one or more product candidates to successfully advance through to approval and licensure could result in the loss of unrecoverable costs expended and impact our ability to generate future revenue from such products, either of which, or both of which, could have an adverse impact on our business. A key part of our business strategy for products in development is to establish collaborative relationships to help fund or manage development and commercialization of our product candidates and research programs. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to continue to develop and commercialize those products and programs, if at all. We have and may in the future need to establish collaborative relationships to obtain domestic and / or international sales, marketing, research, development and distribution capabilities for our products or product candidates and our discovery research programs. Failure to obtain a collaborative relationship for those products or product candidates and programs in markets outside the U. S. requiring extensive sales efforts may significantly impair the potential for those products and programs and we may be required to raise additional capital to continue them. The process of establishing and maintaining collaborative relationships is difficult and time-consuming, and even if we establish such relationships, they may involve significant uncertainty, including: • our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons; • our perceived shortage of capital resources may impact the willingness of companies to collaborate with us; • our contracts for collaborative arrangements are often terminable at will on written notice and may otherwise expire or terminate and we may not have alternative funding available; • our partners may choose to pursue alternative technologies, including those of our competitors; • we may have disputes with a partner that could lead to litigation or arbitration; • we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program; • our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of product candidates, obtain regulatory approvals and successfully manufacture and commercialize the products developed from product candidates; • we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our intellectual property or other proprietary rights or expose us to potential liability; • our partners may not devote sufficient capital or resources towards our product candidates; and • our partners may not comply with applicable government regulatory requirements. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Despite our efforts, we may be unable to secure collaborative arrangements. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital. Even when we are successful in entering into collaboration agreements, collaborations can involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our solely- owned development and commercialization programs, and the financial terms upon which collaborators are willing to enter into such an arrangement cannot be certain. If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. For example, we are working to develop our CpG 1018 adjuvant as a premier vaccine adjuvant through research collaborations, partnerships and supply arrangements. Current relationships and efforts are focused on adjuvanted vaccines for COVID- 19, shingles **and** ~~, Tdap, plague and influenza~~. For some of these relationships, our collaborators have primary responsibility for the development, conduct of clinical trials, and for seeking and obtaining regulatory approval of potential vaccines containing our adjuvant. We have limited or no control over our collaborators' decisions, including the amount and timing of resources that any of these collaborators will dedicate to such activities. In circumstances where our collaborators do not purchase as much adjuvant as we anticipate or they delay placing orders or taking certain deliveries, there can be a negative impact on our revenue recognition. If a collaborator fails to conduct collaborative activities successfully, the development and commercialization of a vaccine could be delayed or may not occur at all. Lastly, the ability of our collaborators to deliver, sell and collect on receivables is not guaranteed and this could, in turn, impact our own ability to collect receivables. Until we are able to generate significant revenues or achieve profitability through product sales on a consistent basis, we may require substantial additional capital to finance our operations. As of December 31, ~~2023~~ **2024**, we had $ ~~742~~ **713**. ~~3~~ **8** million in cash and cash equivalents, and marketable securities. Prior to January 1, 2021, we incurred net losses in each year since our inception. ~~We recorded~~ **While we recognized revenue for the years ended December 31, 2021, 2022 and 2024, we recognized** a net loss of $ 6. 4 million for the year ended December 31, 2023. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of $ ~~930~~ **903**. ~~6~~ **3** million. We expect to continue to incur substantial expenses as we continue to invest in the commercialization and development of HEPLISAV- B and our CpG 1018 adjuvant, clinical trials for our pipeline candidates, and other development. If we cannot generate a sufficient amount of revenue

from product sales, we may need to finance our operations through strategic alliance and licensing arrangements and / or future public or private debt and equity financings. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, our 2. 50 % convertible senior notes due 2026 (" Convertible Notes ") and other securities we issue in the future may have rights senior to those of our common stock and could include covenants that restrict our operations. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. In addition, our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to significantly reduce our operations while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives and the value of our stock. As we plan for the broader commercialization of our HEPLISAV- B vaccine and for the requisite capacity to manufacture our CpG 1018 adjuvant, our financial commitments for manufacturing and supply capacity might outpace actual demand for our products. As we manage our production capabilities for HEPLISAV- B and CpG 1018 adjuvant to support recent market share gains and other initiatives, we have been, and in the future could be, required to make significant financial commitments at our contract manufacturing organizations (" CMOs "), including minimum purchase commitments and prepayments of purchase orders to facilitate the procurement of raw materials and the incurrence of various manufacturing costs. Because of minimum or advance purchase commitments and uncertainty about the expected demand for HEPLISAV- B or CpG 1018 adjuvant, the financial commitments we make to our CMOs to support manufacturing may not be recovered in their entirety, or at all, if our customers do not ultimately purchase from us at expected volumes, or other concessions are made by us. Capacity reservation fees are generally not recoverable if we do not use the capacity we have reserved as a result of lower than expected demand, or otherwise. Similarly, prepayments of purchase orders may not be recoverable if we do not ultimately require the entire volume subject to the applicable purchase order. As a result, we could end up making financial commitments that we never recover if demand for HEPLISAV- B or CpG 1018 adjuvant does not materialize in the volumes we are expecting or at all. This may require us to record certain charges or write-offs in one or more fiscal periods, which in turn could result in significant, unexpected fluctuations in our quarterly and annual operating results, and potentially have a material adverse effect on our results of operations, and financial condition. For example, in August and October 2022, we entered into amendments to the Clover Supply Agreement, which, among other things, modified the scope of the Clover Supply Agreement to reduce certain quantities of CpG 1018 adjuvant that we originally intended to deliver in accordance with a purchase order previously issued by Clover. As a result of the concessions made in the amendments to the Clover Supply Agreement, prior financial commitments made to certain CMOs to manufacture quantities of CpG 1018 adjuvant to fulfill the original Clover purchase order, and reduced demand for CpG 1018 adjuvant, we recorded write- offs of $ 13. 9 million of CpG 1018 adjuvant raw materials inventory and $ 20. 4 million of finished goods inventory during the year ended December 31, 2022. Relating to our Bio E Supply Agreement, we entered into an amendment and an assignment agreement in April 2023, pursuant to which (i) CEPI forgave the entirety of remaining amounts outstanding relating to the Bio E CEPI Advance Payments for CpG 1018 Materials allocated to Bio E and has assumed our previous rights to collect $ 47. 4 million of Bio E accounts receivable, (ii) we collected $ 14. 5 million from Bio E, resulting in no accounts receivable balance as of December 31, **2024 and December 31,** 2023, and (iii) we derecognized a $ 47. 4 million CEPI accrual in connection with the Bio E CEPI Advance Payments. It is possible we may have similar write- offs in the future. We may develop, seek regulatory approval for and market HEPLISAV- B or any other product candidates outside of the U. S., the European Union and ~~Great Britain~~ **the United Kingdom** , requiring a significant additional commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our products or product candidates. We may seek to introduce HEPLISAV- B, or any other product candidates we may develop, to various additional markets in or outside of the U. S., the European Union and ~~Great Britain~~ **the United Kingdom** . Developing, seeking regulatory approval for and marketing our product candidates in or outside of the U. S., the European Union and ~~Great Britain~~ **the United Kingdom** in jurisdictions where we don' t currently have approval could impose substantial costs, impose burdens on our personnel, and divert management' s attention from domestic operations. International operations are subject to risk, including: • the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community; • compliance with varying international regulatory requirements, laws and treaties; • securing international distribution, marketing and sales capabilities upon favorable terms; • adequate protection of our intellectual property rights; • obtaining regulatory and pricing approvals at a level sufficient to justify commercialization; • legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers; • foreign tax compliance and diverse tax consequences; • the fluctuation of conversion rates between foreign currencies and the U. S. dollar; and • regional and geopolitical risks. In the event that we determine to pursue commercialization of HEPLISAV- B outside the United States, the European Union and ~~Great Britain~~ **the United Kingdom** , our opportunity will depend upon our receiving regulatory approval, which can be costly and time consuming, and there is a risk that one or more regulatory bodies may require that we conduct additional clinical trials and / or take other measures which will take time and require that we incur significant additional expense. In addition, we may not receive approval in one or more jurisdictions, even if we undertake these efforts. The results of clinical trials conducted to support regulatory approval in one or more jurisdictions, and any failure or delay in obtaining regulatory approval in one or more jurisdictions, may have a negative effect on the regulatory approval process in other jurisdictions, including our existing regulatory approval in the United States, the European Union and ~~Great Britain~~ **the**

United Kingdom . If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our products or product candidates, which would impair our ability to generate revenues. We rely on CROs and clinical sites and investigators for our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates. We rely on CROs, clinical sites and investigators for our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. While we maintain oversight over our clinical trials and conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third- party contractors to ensure that clinical trials are conducted properly and that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our product candidates and could have a material adverse effect on our business and operations. As a biopharmaceutical company, we engage CROs to conduct clinical studies, and failure by us or our CROs to conduct a clinical study in accordance with GCP standards and other applicable regulatory requirements could result in disqualification of the applicable clinical trial from consideration in support of approval of a potential product. We are responsible for conducting our clinical trials consistent with GCP standards and for oversight of our vendors to ensure that they comply with such standards. We depend on medical institutions and CROs to conduct our clinical trials in compliance with GCP. To the extent that we or they fail to comply with GCP standards, fail to enroll participants for our clinical trials, or are delayed for a significant time in the execution of our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign regulatory authorities, IRBs and the Ethics Committees at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under GMP and other requirements in foreign countries and may require large numbers of participants. In addition, we obtain guidance from regulatory authorities on certain aspects of our clinical development activities and seek to comply with written guidelines provided by the authorities. These discussions and written guidelines are not binding obligations on the part of the regulatory authorities and the regulatory authorities may require additional patient data or studies to be conducted. Regulatory authorities may revise or retract previous guidance during the course of a clinical trial or after completion of the trial. The authorities may also disqualify a clinical trial from consideration in support of approval of a potential product if they deem the guidelines have not been met. The FDA or foreign regulatory authorities may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval. The FDA or other foreign regulatory authorities or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including with respect to our product candidates and those of our partners in combination agent studies: • deficiencies in the trial design; • deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols; • deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold; • a product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks; • the time required to determine whether a product candidate is effective may be longer than expected; • fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments; • a product candidate or combination study may appear to be no more effective than current therapies; • the quality or stability of a product candidate may fail to conform to acceptable standards; • the inability to produce or obtain sufficient quantities of a product candidate to complete the trials; • our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • our inability to obtain IRB or Ethics Committee approval to conduct a clinical trial at a prospective site; • the inability to obtain regulatory approval to conduct a clinical trial; • lack of adequate funding to continue a clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties; • the inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or • the inability to retain participants who have initiated a clinical trial but may withdraw due to side effects from the product, lack of efficacy or personal issues, or who are otherwise unavailable for further follow- up. In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are given to larger patient populations, which often occur in later- stage clinical trials, or less favorable clinical outcomes. Moreover, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate that it be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by a Data Safety Monitoring Board (“ DSMB ”), and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. Any such delay, suspension, termination or request to repeat or redesign a trial could increase our costs and prevent or significantly delay our ability to commercialize our product candidates. Even if we complete all such activities without issue, final results may not actually support approval of a particular product candidate. Our ability to use our net operating loss carryforwards and other tax attributes may be limited. We have incurred significant net operating losses (" NOLs") during our history, and despite prior profitability, may not be able to achieve sustained profitability over the long term. Unused U. S. federal NOLs for taxable years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under legislation enacted in 2017, as modified by legislation

enacted in 2020, U. S. federal NOLs incurred in taxable years beginning after December 31, 2017 can be carried forward indefinitely, but the deductibility of such U. S. federal NOLs in taxable years beginning after December 31, 2020 is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to the aforementioned U. S. tax law provisions. As of December 31, ~~2023~~ **2024**, we had U. S. federal and state NOL carryforwards of $ ~~376~~ **293** . ~~6~~ **5** million and $ ~~283~~ **262** . 9 million, respectively. Of the $ ~~376~~ **293** . ~~6~~ **5** million U. S. federal NOL carryforwards, $ ~~353~~ **293** . ~~5~~ **1** million may be carried forward indefinitely with utilization limited to 80 % of taxable income, and the remainder will begin to expire in ~~2024~~ **2025** . The state NOL carryforwards will begin to expire in ~~2024~~ **2025** . 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 one or more stockholders or groups of stockholders who own at least 5 % of our stock increasing their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period, the corporation' s ability to use its pre- change NOL carryforwards to offset its post- change income or taxes may be limited. We have experienced ownership changes as a result of shifts in our stock ownership in the past, and in the future it is possible that we may be deemed to have experienced additional ownership changes as a result of shifts in our stock ownership, some of which may be outside of our control. This could limit the amount of NOLs that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U. S. tax rules in respect of the utilization of NOLs may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Tax law changes could adversely affect our business and financial condition. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation informally titled the Tax Cuts and Jobs Act of 2017, the 2020 Coronavirus Aid, Relief, and Economic Security Act, and the 2022 Inflation Reduction Act enacted many significant changes to the U. S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of the foregoing tax legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to such legislation or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under past or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense. We **and the third parties supporting our operations** are subject to stringent and evolving U. S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations **(or by the third parties supporting our operations)** could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of business, we process personal data and other sensitive information, including our proprietary and confidential business data, trade secrets, intellectual property, data we may collect about trial participants in connection with clinical trials, and other sensitive data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). In the past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (" CPRA ") (collectively, " CCPA ") requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $ 7, 500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels. These developments may further complicate compliance efforts and may increase legal risk and compliance costs for us and the third parties upon whom we rely **. We may be subject to new laws governing the privacy of consumer health data, including reproductive, sexual orientation, and gender identity privacy rights. For example, Washington' s My Health My Data Act (" MHMD ") broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws. California also recently passed a law protecting privacy of abortion- related records and other reproductive healthcare services. These laws would also apply to our employees in the respective states** . Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union' s General Data Protection Regulation (" EU GDPR "), the United Kingdom' s General Data Protection Regulation (" UK GDPR "), Brazil' s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or " LGPD ")

(Law No. 13, 709 / 2018), and China' s Personal Information Protection Law (" PIPL ") impose strict requirements for processing personal data. For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. ~~In addition, we may be unable to transfer~~ **Regulators in the United States are also increasingly scrutinizing certain** personal data **transfers** ~~from the EEA~~ and **may impose** ~~other jurisdictions to the United States or other countries due to~~ data localization requirements **,** ~~or~~ **for** ~~limitations on cross-~~ **example, the Biden Administration' s executive** ~~border~~ **order Preventing Access** ~~data flows. Although there are various mechanisms that may be used in some cases~~ to ~~lawfully transfer~~ **Americans' Bulk Sensitive** ~~personal~~ **Personal** ~~data~~ **Data and** ~~to the~~ United States ~~or other~~ **Government- Related Data by** ~~countries~~ **Countries of Concern** ~~, these mechanisms are subject to legal challenges and may not be available to us~~. **Outside** ~~An inability or material limitation on our ability to transfer personal data to~~ the United States ~~or other countries could materially impact our business operations. In the ordinary course of business~~ , **certain** ~~we may transfer personal data from the EEA and other jurisdictions to the United States or other countries. We may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross- border data flows. Europe and other~~ jurisdictions have enacted ~~laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their~~ data localization and cross- border data transfer laws **, which could make it more difficult to transfer information across jurisdictions. In particular, the European Economic Area (" EEA") and the U. K. have significantly restricted the transfer of personal data to the United States and other countries whose privacy and data security laws they believe not to offer an adequate level of protection** . Although there are currently various mechanisms that may be used to transfer personal data from the EEA and ~~UK~~ **U. K.** to the United States in compliance with law, such as the **EU** ~~EEA and UK' s~~ standard contractual clauses **, the U. K.' s International Data Transfer Agreement / Addendum and the EU- U. S. Data Privacy Framework and the U. K. extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework)** , these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If **we are unable to implement a legal mechanism to ensure that our transfers of personal data from** ~~there~~ ~~--~~ **the** ~~is no~~ **EEA or the U. K. are** lawful ~~manner~~ **, we could face adverse consequences, including increased exposure to regulatory actions, substantial fines and penalties and injunctions against processing** ~~for~~ ~~--~~ **or** ~~us~~ **transferring personal data, and could be required to increase our data processing capabilities in the EEA, the U. K. or elsewhere at significant expense. Restrictions on our ability** to transfer personal data from the EEA, the **U. K.** ~~UK, or other jurisdictions to the United States, or if the requirements for~~ ~~--~~ **or elsewhere** ~~a legally- compliant transfer are too onerous, we~~ could **impact** ~~face significant adverse consequences, including the interruption or~~ **our clinical trial** ~~degradation of our operations, the need to relocate part of or all of our business or data processing~~ activities ~~to~~ **in** ~~other~~ ~~--~~ **the EEA or** ~~jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties,~~ the **U. K. and limit our** ~~inability~~ ~~--~~ **ability** to **collaborate** ~~transfer data and work~~ with **CROs** ~~partners, vendors~~ and other third parties ~~, and injunctions against our processing or transferring of personal data necessary to operate our business~~ . **We** ~~Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States,~~ are ~~subject to increased scrutiny from regulators, individual litigants, and activist groups. Some regulators in the EEA have ordered certain companies to suspend or permanently cease certain transfers of data out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. On October 7, 2022, President Biden signed an Executive Order on " Enhancing Safeguards for United States Signals Intelligence Activities, " which implements into United States law the agreement in principle announced in March 2022 on a new EU- U. S. Data Privacy Framework. However, if this new transatlantic data transfer framework is not adopted and we are unable to continue to rely on standard contractual clauses or alternative mechanisms of data transfers from the EEA to the United States, this may materially and adversely affect our business, financial condition, and results of operations. Additional privacy advocates and industry groups have proposed, and may propose in the future, standards with which we are legally or contractually bound to comply. In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may be subject to contractual obligations and policies related to data privacy and security. We may~~ also ~~be~~ bound by ~~other~~ contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the ~~EU~~ GDPR and ~~UK GDPR~~ **the CCPA** , require our customers to impose specific contractual restrictions on their service providers. ~~Data~~ **We publish** privacy **policies** ~~and security laws are quickly changing~~ , **marketing materials** and **other statements, such as** compliance ~~(and any perceived non~~ **with certain certifications or self** - **regulatory principles, regarding** ~~compliance) is costly. Although we endeavor to comply with all applicable~~ data privacy and security ~~obligations,~~ **. If** these ~~obligations~~ **policies, materials or statements** are **found** ~~quickly changing in an increasingly stringent fashion, creating some uncertainty as~~ to ~~how to comply. Additionally, these obligations may~~ be ~~subject to differing applications and interpretations~~ **deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may face adverse consequences** , which may **include** ~~be inconsistent or conflict among jurisdictions. If we or the third parties on which we rely fail~~ , ~~or~~ **but** are ~~perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but~~ not limited to, ~~government~~ **governmental** enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar) ~~;~~ **,** litigation (including class- related claims) ~~;~~ **and mass arbitration demands,** additional reporting requirements and / or oversight ~~;~~ **,** bans on processing personal data ~~;~~ **,** orders to destroy or not use personal data ~~;~~ **, civil and criminal liability** and imprisonment of company officials **. In particular, plaintiffs**

have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations . Any of these events could have a material adverse effect on our reputation, business ~~,~~ or financial condition, including but not limited to ~~: loss of customers;~~ interruptions or stoppages in ~~our~~ business operations ~~,~~ **(** including ~~our~~ clinical trials ~~;~~ **), inability to process personal data or to operate in certain jurisdictions, limited ability to develop or commercialize our products,** expenditure of time and resources to defend any claim or inquiry ~~; adverse publicity;~~ or revision or restructuring of our operations **. In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply or may become subject to in the future. Our obligations related to privacy and data security are quickly changing and becoming increasingly stringent, creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may also necessitate changes to our information technologies, systems and practices and those of third parties upon which we rely. Moreover, despite our efforts, our personnel or third parties upon which we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For instance, in the European Union, the second Network and Information Security Directive (Directive (EU) 2022 / 2555, " NIS2 ") entered into force on 17 January 2023 and had to be transposed into the national law of each Member State by 17 October 2024. NIS2 creates a specific legal framework for the resilience and incident response capabilities of entities operating in 18 sectors, including the health sector. As a result, companies in scope are obligated to maintain robust network and information systems security measures and report any significant incidents that might impact their operations. Companies that fail to comply with NIS2 may face significant operational disruptions, legal liabilities, and regulatory penalties of a maximum of € 10 million or up to 2 % of the total worldwide turnover of the preceding financial year. Our employees and other personnel can use generative artificial intelligence (" AI ") technologies, from time to time, in certain circumstances to perform portions of their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. Our use of generative AI could make it more difficult to comply with various privacy laws and other privacy obligations in the U. S. and Europe and could negatively affect our ability to protect or own certain intellectual property, any or all of which may cause us to incur significant expense, cause reputational damage, and otherwise adversely affect our business** . If we fail to comply with the extensive requirements applicable to biopharmaceutical manufacturers and marketers under the healthcare fraud and abuse, anticorruption, privacy, transparency and other laws of the jurisdictions in which we conduct our business, we may be subject to significant liability. Our activities, and the activities of our agents, including some contracted third parties, are subject to extensive government regulation and oversight both in the U. S. and in foreign jurisdictions. Our interactions with physicians and others in a position to prescribe or purchase our products are subject to a legal regime designed to prevent healthcare fraud and abuse and off- label promotion. We also are subject to laws pertaining to transparency of transfers of value to healthcare providers; privacy and data protection; compliance with industry voluntary compliance guidelines; and prohibiting the payment of bribes. Relevant U. S. laws include: • the federal Anti- Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as the Medicare and Medicaid programs; • federal false claims laws, including the False Claims Act and Civil Monetary Penalties Law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent; • the Federal Food, Drug and Cosmetic Act and governing regulations which, among other things, prohibit off- label promotion of prescription drugs; • the federal Physician Payments Sunshine Act created under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education and Reconciliation Act of 2010 (collectively, " ACA ") which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members; • the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which created, among other things, new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which imposes certain requirements on " covered entities, " including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective " business associates " that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors relating to the privacy, security, and transmission of individually identifiable health information; • the Foreign Corrupt Practices Act, which prohibits the payment of bribes to foreign government officials and requires that a company' s books and records accurately reflect our transactions; and • foreign and state law equivalents of each of the federal laws described above, such as anti- kickback and false claims laws which may apply to items or services reimbursed by state health insurance programs or any third- party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s

voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information on the pricing of certain drugs; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. In the U. S., the Office of Inspector General for the Department of Health and Human Services, the Department of Justice, states' Attorneys General and other governmental authorities actively enforce the laws and regulations discussed above. These entities also coordinate extensively with the FDA, using legal theories that connect violations of the Federal Food, Drug and Cosmetic Act (such as off- label promotion) to the eventual submission of false claims to government healthcare programs. Prosecution of such promotion cases under the False Claims Act provides the potential for private parties (qui tam relators, or " whistleblowers ") to initiate cases on behalf of the government and provides for significantly higher penalties upon conviction. In the U. S., pharmaceutical and biotechnology companies have been the target of numerous government prosecutions and investigations alleging violations of law, including claims asserting impermissible off- label promotion of pharmaceutical products, payments intended to influence the referral of federal or state health care business, submission of false claims for government reimbursement, or submission of incorrect pricing information. Violations of any of the laws described above or any other applicable governmental regulations and other similar foreign laws may subject us, our employees or our agents to significant criminal, civil and administrative penalties, including fines, civil monetary penalties, exclusion from participation in government health care programs (including, in the U. S., Medicare and Medicaid), disgorgement, imprisonment, 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 restriction or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Additionally, whether or not we have complied with the law, an investigation into alleged unlawful conduct may cause us to incur significant expense, cause reputational damage, divert management time and attention, and otherwise adversely affect our business. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants, contractors, or other agents are or will be in compliance with all applicable U. S. or foreign laws. We have applied for, and in some cases have received, grants that, if and when received, may involve pricing or other restrictions. We have applied for, and in some cases have received, grants from various charitable, philanthropic and other organizations that, if and when received, may come with certain pricing requirements, global access requirements, reporting requirements or other covenants that require us to make the funded product available worldwide and on a nondiscriminatory basis. For example, we received such an initial grant from the Bill and Melinda Gates Foundation in 2020 to help fund the potential scale- up of production of our CpG 1018 adjuvant that may be required in the event the CpG 1018 adjuvant is included in any approved and commercially available vaccine, whether a COVID- 19 vaccine or otherwise. Covenants in these types of grants may limit the price we can charge for any funded product and may involve a license to use technology we own that is included in the funded products if we do not comply. Such price limitations or licenses, if invoked, could serve to limit the prices we charge, or our control over the manufacturing and distribution of grant-funded products. Failure to agree to such requirements, may result in us not receiving some or all of the grant. Enacted or future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may have an adverse effect on our operations and business. We expect there will continue to be federal and state laws and / or regulations, proposed and implemented, that could impact our operations and business. For example, the ACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. There have been executive, legal and political challenges **and amendments** to certain aspects of ACA ~~. For example, President Trump signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of ACA. While 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 Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax- based shared responsibility payment imposed by 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, effective January 1, 2020, the ACA- mandated " Cadillac " tax on high- cost employer- sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018 among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole. " On June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. In addition, the ACA has been subject to various health reform measures~~ . For example, on August 16, 2022, ~~President Biden signed~~ the Inflation Reduction Act of 2022 (" IRA ") **was signed** into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program. It is unclear how any such challenges and additional healthcare reform measures by the ~~Biden~~ **second Trump** administration will impact the ACA and our business. Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, ~~President Biden signed~~ the American

Rescue Plan Act of 2021 **was signed** into law, which ~~eliminates~~ **eliminated** the statutory Medicaid drug rebate cap, ~~currently~~ **previously** set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. ~~In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding.~~ Also, there has been heightened governmental scrutiny recently in the U. S. over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. **For example, the IRA** ~~Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to~~ , among other things, **(i) directs** ~~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, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021,~~ the U. S. Department of Health and Human Services (" HHS ") ~~released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (i) directs HHS~~ to negotiate the price of certain ~~drugs and~~ biologics covered under Medicare **that have been on the market for at least 11 years (the " Medicare Drug Price Negotiation Program ")** , and subjects drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. ~~The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.~~ These provisions **began to** take effect progressively ~~starting~~ in 2023 **, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges** . On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list~~ **agree-upon price** of the first ten drugs that **were** ~~will be~~ subject to price negotiations, ~~although~~ **which take effect in January 2026. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to** the Medicare ~~drug~~ **Drug** ~~pricing~~ **Price** ~~negotiation~~ **Negotiation** ~~program~~ **Program** ~~is currently subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services (" CMS") Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future~~ . Further, on December 7, 2023, ~~the Biden administration announced~~ an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act **was announced** . On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, and restrictions on certain product access. In some cases, such legislation and regulations have been designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida' s Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU 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. We cannot predict the initiatives that may be adopted in the future or the effect any such initiatives may have on our business. However, in the future, there will likely continue to be additional proposals relating to the reform of the U. S. healthcare system, **particularly in light of the recent U. S. Presidential and Congressional elections** and other equivalent foreign systems, some of which could further limit coverage and reimbursement of products, including our **product candidates. For example, the newly elected Presidential administration may be more skeptical of the safety and efficacy of vaccine products, which could lead to increased regulatory scrutiny and more restrictive coverage policies regarding our products and** product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. In connection with our work with the U. S. Department of Defense (" DoD"), we have become a defense contractor, and are therefore subject to additional administrative burdens and control requirements in connection with the maintenance of that relationship. In September 2021, we entered into an agreement with the DoD relating to the conduct of a clinical trial and studies in connection with the development of an improved plague vaccine **. In July 2023, we entered into a contract modification with the DoD to support advancement into a nonhuman primate challenge study, and in December 2024, we entered into an agreement with the DoD to support additional Phase 2 clinical and manufacturing activities to be performed through the first half of 2027** . In connection with

this agreement, we became subject to new administrative and control requirements, including certain reporting obligations as well as a requirement to develop, implement and maintain an International Traffic in Arms Regulations compliance program, among other things. Further, if our efforts result in an improved plague vaccine and we enter into a supply agreement for finished plague vaccines with the DoD, we expect that such a supply contract would impose additional administrative, control, compliance and other obligations. We have limited experience developing and administering such programs. Development and maintenance of such programs can be burdensome and costly and there can be no guarantee that we will be able to maintain compliance with all of the terms of such an agreement. **As a federal government contractor, we also maintain plans to ensure compliance with nondiscrimination and regulatory requirements for qualified employees on the basis of gender, race, disability, and veteran status. Consequently, we may be subject to executive orders and regulatory changes affecting various aspects of our operations, including compliance with nondiscrimination plans. Any required elimination or modification of such plans in response to new executive orders could pose challenges in hiring or retaining employees, and may lead to other adverse operational impacts.** Failure to comply with ~~these~~ requirements **applicable to us as a federal contractor could expose us to administrative, civil, or criminal liabilities, including fines, penalties, repayments, or suspension or debarment from eligibility for future U. S. government contracts and** could have a significant reputational or financial impact on our business and on our stock price. We face product liability exposure, which, if not covered by insurance, could result in significant financial liability. While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products, including HEPLISAV- B, will subject us to potential product liability claims and may raise questions about a product' s safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited clinical trial liability and umbrella insurance coverage for our clinical trials. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost, or at all. While we have obtained product liability insurance coverage for HEPLISAV- B, there is a risk that this coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management' s attention from our business and could result in significant financial liability. Risks Related to our Intellectual Property If third parties assert that we have infringed their patents or other proprietary rights or challenge our patents or other proprietary rights, we may become involved in disputes and litigation that would be costly, time consuming and have a negative impact on the commercialization of our current products and delay or prevent development or commercialization of our product candidates. We may be exposed to future litigation or other dispute with third parties based on claims that our products, product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the ownership, scope or validity of our or another party' s proprietary rights, including a challenge as to the validity and scope of our issued and pending claims. From time to time, we have been, and in the future may become, involved in various administrative proceedings related to our intellectual property which can cause us to incur certain legal expenses. If we become involved in any litigation and / or other administrative proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel. If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in connection with the commercialization of HEPLISAV- B or any similar or other product candidate, we or our collaborators could be required to pay substantial damages or be unable to commercialize our product candidates or use our proprietary technologies without a license from such third party. A license may require the payment of substantial fees or royalties, require a grant of a cross- license to our intellectual property or technologies or may not be available on acceptable terms, if at all. Any of these outcomes could require us to change our business strategy and could materially impact our business, operations or financial condition. If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our products or product candidates may decrease, and we may be unable to realize any commercial benefit from the development of our products or product candidates. Our success depends on our ability to: • obtain and protect commercially valuable patents or the rights to patents both domestically and abroad; • operate without infringing upon the proprietary rights of others; and • prevent others from successfully challenging or infringing our proprietary rights. We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents for a commercially sufficient term or are otherwise effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U. S. and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, or other disclosures which impact patentability, which may only allow us to obtain relatively narrow patent protection, if any at all. In the U. S., and worldwide, legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in U. S. patent and ex- U. S. patent laws could diminish the value of patents in general, thereby impairing us and our collaborators' ability to protect our products. Our HEPLISAV- B vaccine and CpG 1018 adjuvant have no composition of matter patent protection in the United States or elsewhere. We must therefore rely primarily on the protection afforded by method of use patent claims relating to HEPLISAV- B vaccine and the use of CpG 1018 adjuvant in vaccines, and trade secret protection and confidentiality and other agreements to protect our interests in proprietary know- how related to HEPLISAV- B vaccine and CpG 1018 adjuvant. We have three issued U. S. patents relating to certain uses of HEPLISAV- B that are projected to expire in 2032. We have filed patent applications claiming compositions and methods of use of CpG 1018

adjuvant for COVID- 19 and other vaccines, but we cannot provide any assurances that we will receive an issued patent for any of these patent applications or that, if issued, any of these patents will provide adequate protection for any intended use of CpG 1018 adjuvant in vaccines. In addition, we are or may be subject to co- ownership of the underlying intellectual property with our collaborators and, therefore, may not be the sole owner and be in a position to diligently control patent prosecution, or enforce our rights. If we are unable to adequately obtain patent protection or enforce our other proprietary rights relating to CpG 1018 adjuvant, we may be unable to realize any recurring commercial benefit from the development of a vaccine containing CpG 1018 adjuvant, and we may not have the ability to prevent others from developing or commercializing a vaccine containing CpG 1018 adjuvant. We also rely on trade secret protection and confidentiality and other agreements to protect our interests in proprietary know- how related to CpG 1018 adjuvant. If we or our collaborators are unable to adequately obtain, protect or enforce our proprietary rights relating to CpG 1018 adjuvant, we may be unable to realize recurring commercial benefit from the development of a vaccine containing CpG 1018 adjuvant, and we or our collaborators may not have the ability to prevent others from developing or commercializing a vaccine containing the adjuvant. Disputes or litigation may also arise with our collaborators (with us and / or with one or more third parties), including disputes over ownership rights to intellectual property, know- how or technologies developed with our collaborators. Because patent applications in the U. S. and many foreign jurisdictions typically are not published until 18 months after filing and publications of discoveries in the scientific literature lag behind actual discoveries, we cannot be certain that we were the first to file for protection of the inventions set forth in these patent applications or in our issued patents. Further, there could be post- grant proceedings such as inter partes review (" IPR"), post grant review (" PGR"), reexamination, reissue or opposition which could result in claims in our patents being narrowed or invalidated. Our commercial success depends significantly on our ability to operate without infringing patents and other proprietary rights of third parties. A number of pharmaceutical companies and biotechnology companies, as well as universities and research institutions, may have filed patent applications or may have been granted patents that cover inventions similar to the inventions owned by or licensed to us. We may not be able to determine with certainty whether patents or patent applications of other parties may materially affect our ability to make, use, offer to sell, or sell any products. If another party controls patents or patent applications covering our products, we may not be able to obtain the rights we need to those patents or patent applications in order to commercialize our products. Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party' s proprietary rights. The existence of third- party patent applications and patents could significantly reduce the coverage of the patents owned by or licensed to us and limit our ability to obtain meaningful patent protection. Litigation or any other proceedings could result in substantial costs to and diversion of effort by us, and an adverse outcome in a court or patent office could subject us to significant liabilities, require disputed rights to be licensed from other parties, or require us to cease using some of our technology. We may not prevail in these actions or proceedings if they arise. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or our licensors. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following: • we may not receive an issued patent for any of our patent applications or for any patent applications that we may have exclusively licensed, now or in the future; • the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents; • the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable; • we might not be able to develop additional proprietary technologies that are patentable; • the patents licensed or issued to us or our collaborators may not provide a competitive advantage; • patents issued to other parties may limit our intellectual property protection or harm our ability to do business; • other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; • other parties may design around technologies we have licensed, patented or developed; • pending patent applications or issued patents may be challenged by third parties in litigation or other proceedings, such as inter partes reviews, pre- and post- grant oppositions, reexaminations, derivation proceedings and post- grant review, in the U. S or abroad; • we may be subject to claims that our employees or consultants have used or disclosed trade secrets or other proprietary information of their former employers or clients, thus putting our intellectual property at risk; • our reliance on trade secret protection and confidentiality and other agreements may not be sufficient to protect our interests and proprietary know- how related to our products and processes; and • it may be found that we or our collaborators have not complied with various procedural, document submission, fee payment and other requirements imposed by patent offices, and our patent protection could be reduced or eliminated. We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know- how that may not be directed to what is considered to be patentable subject matter, and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets or other proprietary know- how adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary rights, we may be unable to commercialize or continue to commercialize our products, enter into or maintain collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors. We have in the past, and may in the future, rely on licenses to intellectual property from third parties. Impairment of these licenses or our inability to obtain or maintain them could severely harm our business. Our current or future research and development efforts may depend in part upon our license arrangements for certain intellectual property owned by or co- owned with third parties. Our dependence on these licenses could subject us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements could require us to make timely payments to maintain our licenses and typically contain diligence or milestone- based termination provisions. Our failure to meet any obligations pursuant to such agreements could allow licensors to terminate our agreements or undertake other remedies such as converting exclusive to non- exclusive licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us or at all. In addition, license agreements may be terminated or may expire by their terms, and we may not be

able to maintain the exclusivity of these licenses or any rights to the underlying intellectual property. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our products or product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products or product candidates. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to develop or commercialize certain of our products or product candidates. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third- party' s intellectual property (including patents), which may not be possible or could require substantial funds and time. We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel. Many of our employees or consultants may have been previously employed in other biopharmaceutical companies, including our competitors or potential competitors. Some of these individuals executed proprietary rights, non- disclosure and non- competition agreements in connection with such previous employment or engagements. Although no claims against us are currently pending, we may be subject to claims that these employees or consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or clients. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to develop and ultimately commercialize, or prevent us from developing and commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. We may rely, in some circumstances, on trade secrets and confidentiality agreements to protect our technology. Although trade secrets are difficult to protect, wherever possible, we use confidential disclosure agreements to protect the proprietary nature of our technology. Our standard practice is to require each of our collaborators, commercial partners, employees, consultants, contractors and advisors to enter into an agreement before beginning their employment, consulting or advisory relationship with us that in general provides that the individuals must keep confidential and not disclose to other parties any of our confidential information developed or learned by the individuals during the course of their relationship with us except in limited circumstances. These agreements with employees, consultants and contractors also generally provide that we own all inventions conceived by the individuals in the course of rendering their employment or services to us. However, there can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and / or proprietary information will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know- how and inventions, which could result in substantial costs which could severely harm our business. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications are due to be paid to the United States Patent and Trademark Office and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and / or applications. We employ reputable law firms and other professionals to help us comply, and in many cases an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdictions, and in such an event, our competitors might be able to enter the market. We may not be able to protect our intellectual property rights throughout the world. The biopharmaceutical patent environment outside the U. S. is also uncertain. We may be particularly affected by this uncertainty since several of our product candidates or our collaborators' vaccine candidates may initially address market opportunities outside the U. S., where we may only be able to obtain limited patent protection, if any at all. For example, while many countries such as the U. S. permit method of use patents or patent claims relating to the use of drug products, in some countries the law relating to patentability of such use claims is evolving, or may prohibit certain activities, and may be unfavorably interpreted to prevent us from successfully prosecuting some or all of our pending patent applications. There are some countries that currently do not allow such method of use patents or patent claims, or that significantly limit the types of uses, claims or subject matter that are patentable. Patents are of national or regional effect. Filing, prosecuting and defending patents on all of our products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U. S. can be less extensive than those in the U. S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S. or from selling or importing products made using our inventions in and into the U. S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U. S. These competitor products may compete with our products and product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Geo- political actions in the U. S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to

pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. Various countries outside the U. S. have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. 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. Further, the standards applied by the USPTO, foreign patent offices and other adjudicating bodies in granting and / or adjudicating patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our products and product candidates. Changes in U. S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the U. S. or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the U. S., numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the America Invents Act, involved significant changes in patent legislation. Additionally, the U. S. Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. For example, in Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications 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. Risks Related to our Common Stock Our stock price is subject to volatility, and your investment may suffer a decline in value. The market prices for securities of biopharmaceutical companies have in the past been, and are likely to continue in the future to be, very volatile. The market price of our common stock is subject to substantial volatility depending upon many factors, many of which are beyond our control, including: • **our ability to expand or retain our HEPLISAV- B vaccine market share; •** impact of COVID- 19 or other respiratory or seasonal vaccination initiatives on our HEPLISAV- B vaccine, CpG 1018 adjuvant, or other product revenue; • progress or results of any of our clinical trials or regulatory or manufacturing efforts, in particular any announcements regarding the progress or results of our planned trials and BLA filing and communications, from the FDA or other regulatory authorities; • our ability to receive timely regulatory approval for our product candidates; • our ability to establish and maintain collaborations for the development and commercialization of our product candidates; • our ability to raise additional capital to fund our operations, to the extent needed; • technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors; • changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates; • our ability to obtain component materials and successfully enter into manufacturing relationships for our products or product candidates or establish manufacturing capacity on our own; • our ability to establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates; • changes in government regulations, general economic conditions or industry announcements; • changes in the structure of healthcare payment systems; • issuance of new or changed securities analysts' reports or recommendations **; • accumulations of our common stock or other public actions by our shareholders and related market or investor perceptions and expectations, some of which may be speculative or short term in nature** ; • actual or anticipated fluctuations in our quarterly financial and operating results; • the volume of trading in our common stock; • investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance; and • industry conditions and general financial, economic and political instability. The stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies. Changes in the broader macroeconomic condition, including historically high inflation, changes in interest rates, government ~~tapering~~ policies, impact of pandemics or endemics and instances of geopolitical instability, such as that resulting from the conflicts in the Middle East and Ukraine, can and have caused changes in market prices, notwithstanding a lack of fundamental change in the underlying business models or prospects of companies. These broad market fluctuations have adversely affected and may in the future adversely affect the market price of our common stock, regardless of our actual operating performance. One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action and shareholder derivative litigation have often been brought against a company following a decline in the market price of its securities. We have in the past been, and we may in the future be, the target of such litigation. Securities and shareholder derivative litigation could result in substantial costs, and divert management' s attention and resources, which could harm our business, operating results and financial condition. Future sales of our common stock or the perception that such sales may occur in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Under our universal shelf registration statement, we may sell any combination of common stock, preferred stock, debt securities and

warrants in one or more offerings, including pursuant to our sales agreement with Cowen & Company, LLC, under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $ 120. 0 million. As of December 31, ~~2023~~ **2024** , we had ~~approximately~~ $ 120. 0 million of our common stock remaining available for future issuance under our sales agreement with Cowen & Company, LLC. The sale or issuance of our securities, ~~including those issuable upon exercise of the outstanding warrants or conversion of the preferred stock,~~ as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities. **There can be no assurance with respect to the number of shares of our common stock repurchased under the share repurchase program or that our share repurchase program will provide the benefits anticipated. In November 2024, our Board of Directors authorized a share repurchase program to repurchase up to $ 200. 0 million of our common stock, subject to market conditions. We can provide no assurance with respect to the number of shares of our common stock repurchased under the share repurchase program or that our share repurchase program will provide the benefits anticipated, and it may not prove to be the best use of our cash. The program could affect the trading price of our stock and increase volatility, and any announcement of a termination of this program may result in a decrease in the trading price of our stock. In addition, this program will reduce our cash reserves. The anti- takeover provisions of our certificate of incorporation, our bylaws, Delaware law and our stockholder rights plan may prevent or frustrate a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management. Provisions of our certificate of incorporation and bylaws may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting or other rights of the holders of our common stock. These provisions include: • authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors; • limiting the persons who can call special meetings of stockholders; • prohibiting stockholder actions by written consent; • a classified Board of Directors pursuant to which our directors are elected for staggered three year terms; • providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and • establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings. Our limited duration stockholder rights plan also may have certain anti- takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that acquires beneficial ownership of more than a specified percentage of our outstanding common stock without the prior approval of our Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition, or may be redeemed by us, the rights plan may deter certain parties from pursuing strategic transactions involving us, including potential acquisitions. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15 % or more of our common stock for three years unless the holder' s acquisition of our stock was approved in advance by our Board of Directors.** Risks Related to Our Outstanding Convertible Notes Servicing our ~~debt~~ **Convertible Notes** requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the $ 225. 5 million in Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. We may not have the ability to generate or raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the notes for cash upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Convertible Notes. Holders of the Convertible Notes will have the right, subject to certain conditions and limited exceptions, to require us to repurchase all or a portion of their Convertible Notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100 % of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. Moreover, we will be required to repay the Convertible Notes in cash at their maturity unless earlier converted, redeemed or repurchased. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefore or pay cash with respect to Convertible Notes being converted. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the indenture governing the Convertible Notes or to pay any cash payable on future conversions of the Convertible Notes as required by the indenture governing the Convertible Notes would constitute a default under the indenture governing the Convertible Notes. A default under the indenture governing the Convertible Notes or the occurrence of a fundamental change itself could also lead to a default under agreements governing our future indebtedness. Moreover, the occurrence of a fundamental change under the indenture governing the Convertible Notes could constitute an event of default under any agreements governing our future indebtedness. If the repayment of the related

indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof. The conditional conversion feature of the Convertible Notes may adversely affect our financial condition and operating results. From ~~October~~ **January** 1 through December 31, ~~2023~~ **2024** , the conditions allowing holders to convert all or any portion of their Convertible Notes were not met. In the event the conditional conversion feature of the Convertible Notes is triggered, holders of Convertible Notes will be entitled to convert their Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long- term liability, which would result in a material reduction of our net working capital. Conversion of the Convertible Notes may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock. From ~~October~~ **January** 1 through December 31, ~~2023~~ **2024** , the conditions allowing holders to convert all or any portion of their Convertible Notes have not been met. In the event the conditional conversion feature of the Convertible Notes is triggered, the conversion of some or all of the Convertible Notes to shares of common stock may dilute the ownership interests of our stockholders. Upon conversion of the Convertible Notes, we have the option to pay or deliver, as the case may be, cash, shares of our common stock, or a combination of cash and shares of our common stock. If we elect to settle our conversion obligation in shares of our common stock or a combination of cash and shares of our common stock, any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could be used to satisfy short positions, or anticipated conversion of the Convertible Notes into shares of our common stock could depress the price of our common stock. Certain provisions in the indenture governing the Convertible Notes may delay or prevent an otherwise beneficial takeover attempt of us. Certain provisions in the indenture governing the Convertible Notes may make it more difficult or expensive for a third party to acquire us. For example, the indenture governing the Convertible Notes will require us, subject to certain exceptions, to repurchase the Convertible Notes for cash upon the occurrence of a fundamental change and, in certain circumstances, to increase the conversion rate for a holder that converts its Convertible Notes in connection with a make- whole fundamental change. A takeover of us may trigger the requirement that we repurchase the Convertible Notes and / or increase the conversion rate, which could make it more costly for a potential acquirer to engage in such takeover. Such additional costs may have the effect of delaying or preventing a takeover of us that would otherwise be beneficial to investors. The Capped Calls may affect the value of the Convertible Notes and our common stock. In connection with the issuance of the Convertible Notes, we have entered into capped call transactions with the option counterparties totaling $ 27. 2 million (the" Capped Calls"). The Capped Calls cover, subject to customary adjustments under the terms of the Capped Calls, the number of shares of common stock that initially underlie the Capped Calls. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price. In connection with establishing their initial hedges of the Capped Calls, we have been advised that the option counterparties and / or their respective affiliates entered into various derivative transactions with respect to our common stock concurrently with or shortly after the pricing of the Convertible Notes and / or purchased shares of our common stock concurrently with or shortly after the pricing of the Convertible Notes. In addition, the option counterparties and / or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions following the pricing of the Convertible Notes and prior to the maturity of the Convertible Notes (and are likely to do so on each exercise date of the Capped Calls, which are expected to occur during the 30 trading day period beginning on the 31st scheduled trading day prior to the maturity date of the Convertible Notes, or following any termination of any portion of the Capped Calls in connection with any repurchase, redemption or early conversion of the Convertible Notes). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Convertible Notes. We are subject to counterparty risk with respect to the capped call transactions. The option counterparties are financial institutions, and we will be subject to the risk that any or all of them might default under the Capped Calls. Our exposure to the credit risk of the option counterparties will not be secured by any collateral. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the Capped Calls with such option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the option counterparties. General Risk Factors The loss of key personnel could delay or prevent achieving our objectives. In addition, our continued growth to support commercialization may result in difficulties in managing our growth and expanding our operations successfully. We depend on our senior executive officers, as well as other key scientific personnel. Our commercial and business efforts could be adversely affected by the loss of one or more key members of our commercial or management staff, including our senior executive officers. We currently have no key person insurance on any of our employees. As our operations expand, we expect that we will need to manage additional relationships with various vendors, partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to successfully commercialize HEPLISAV- B, or other future products we may attempt to commercialize, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to effectively manage our commercialization efforts, research efforts and

clinical trials and hire, train and integrate additional regulatory, manufacturing, administrative, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing and achieving profitability. Our business operations are vulnerable to interruptions by natural disasters, health epidemics and other catastrophic events beyond our control, the occurrence of which could materially harm our manufacturing, distribution, sales, business operations and financial results. Our business operations are subject to interruption by natural disasters and other catastrophic events beyond our control, including, but not limited to, earthquakes, hurricanes, fires, droughts, tornadoes **, tsunamis** , electrical blackouts, public health crises and pandemics, war, terrorism, bank failures and geo- political unrest and uncertainties. We have not undertaken a systematic analysis of the potential consequences to our business that might result from any such natural disaster or other catastrophic event and have limited recovery plans in place. If any of these events occur, our manufacturing and supply chain, distribution, sales and marketing efforts and other business operations could be subject to business shutdowns or disruptions and financial results could be adversely affected. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions resulting from these events, but if we or any of the third parties with whom we engage, including the suppliers, contract manufacturers, distributors and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and adversely affected in a number of ways, some of which are not predicable. Our business could be adversely affected by health epidemics in regions where we have manufacturing facilities, sales activities or other business operations. For example, outbreaks of epidemic or pandemic diseases, such as COVID- 19, or the fear of such events, have and could again in the future cause restrictions on supply chains, restrict access to workplaces and affect employee health and availability. Furthermore, during the peak of the COVID- 19 pandemic there was a significantly reduced utilization of all adult vaccines (other than COVID- 19 vaccines), including a reduced utilization of HEPLISAV- B. Although we maintain inventories of HEPLISAV- B and its components, our ability and those of our contractors and distributors to produce and distribute HEPLISAV- B could be adversely affected. A pandemic or similar health challenge could severely impact the U. S. healthcare system, which may have an adverse effect on usage and sales of HEPLISAV- B. In addition, any such event could result in widespread global health crisis that could adversely affect global economies and financial markets resulting in an economic downturn that could affect the demand for HEPLISAV- B and future revenue and operating results and our ability to raise additional capital when needed on acceptable terms, if at all. Additionally, our corporate headquarters in Emeryville, California, is located in a seismically active region that also is subject to possible electrical shutdowns and wildfires. Because we do not carry earthquake insurance for earthquake- related losses and significant recovery time could be required to resume operations, our financial condition and operating results could be materially adversely affected in the event of a major earthquake or catastrophic event. We carry only limited business interruption insurance that would compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us in excess of insured amounts could adversely affect our business and operations. If our information technology systems or those of third parties upon which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. Our business is increasingly dependent on critical, complex and interdependent information technology systems, including internet- based systems, to support business processes as well as internal and external communications. In addition, our dependence on information technology systems has intensified because many of our critical business activities are now being conducted remotely in our remote- first work environment. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses that may result in the impairment of key business processes. In addition, our systems, along with those of our customers, suppliers, or third- party service providers which operate critical business systems to process sensitive information in a variety of contexts are potentially vulnerable to a variety of evolving threats and data security breaches — whether by employees or others — that may expose sensitive data to unauthorized persons. Such threats could include, but not be limited to social- engineering attacks (including through phishing attacks), online and offline fraud, malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks, access attacks (such as credential stuffing or credential harvesting), personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Ransomware attacks, including by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable flaws or bugs that could result in a breach of or disruption to our information technology systems (including our products or the third- party information technology systems that support us and our goods). **We rely on third parties to operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place.** If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related

obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. **It may be difficult and / or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.** The potential liability and associated consequences we could suffer as a result of any such cyber events could be catastrophic and result in irreparable harm including (a) the loss of trade secrets or other intellectual property, or (b) the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others, (c) extortion and other monetary damages due to malware or business email compromise, (d) significant interruptions in our operations, or (e) other significant damages. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal, state and / or international data breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, including, but not limited to, HIPAA, similar state data protection regulations, and the EU GDPR and UK GDPR, resulting in significant penalties; increased costs; loss of revenue; expenses of computer or forensic investigations; material fines and penalties; compensatory, special, punitive or statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and / or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; or injunctive relief. 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. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. U. S. and equivalent foreign authorities and international authorities warned businesses of increased cybersecurity threats from actors seeking to exploit the COVID- 19 pandemic. **If** ~~In 2020, we experienced a cybersecurity incident known as a phishing e- mail scam, and although we do not consider its impact on us to be material, if~~ we are unable to prevent ~~this or other such~~ data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. Moreover, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory scrutiny. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures that are intended to protect our data security and information technology systems, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Adverse developments affecting the financial services industry may have adverse consequences on our business, financial condition and stock price. We regularly maintain cash balances at third- party financial institutions in excess of the FDIC insurance limit. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. ~~55~~