

Risk Factors Comparison 2025-03-04 to 2024-03-08 Form: 10-K

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The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The occurrence of any of the following risks or of unknown risks and uncertainties may adversely affect our business, operating results and financial condition. **RISK FACTOR SUMMARY** ~~There are~~ **This risk factor summary contains a number of high-level summary** ~~of government contracting risks~~ **associated with our business. It does not contain all of the information** ~~that could impact our business~~ **may be important to you.** ~~financial condition, operating results and cash flows~~ **you should read this risk factor summary together with the more detailed discussion of risks and uncertainties set forth following this summary. A summary of our risks includes** ~~including but is not limited to, the following~~: • Reduced demand for and / or funding for procurement of CYFENDUS ®, **ACAM2000 ®, VIGIV CNJ- 016 ®, BAT ®** and / or BioThrax ®, ~~vaccines or ACAM2000 ® and~~ discontinuation of funding of our ~~other~~ **USG procurement and development contracts.** • Inability to secure follow-on product procurement contracts with the USG upon the expiration of any of our existing procurement contracts. ~~There are a number of manufacturing risks that could impact our business, financial condition, operating results and cash flows, including:~~ • Our inability to maintain quality and **compliance in all of our manufacturing compliance operations.** • **Damage to, destruction of, or any unplanned disruption** at our manufacturing facilities for our products and for product candidates for our Bioservices customers. • ~~Disruption at, damage to or destruction of~~ our development and / or manufacturing facilities may impede our ability to manufacture our products, as well as deliver our bioservices. • Our operations, including our use of hazardous materials, chemicals, bacteria and viruses expose us to significant potential liabilities. ~~There are a number of product development and commercialization risks that could impact our business, financial condition, operating results and cash flows, including:~~ • Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. • We may fail to capitalize on the most scientifically, clinically or commercially promising or profitable product candidates. ~~There are a number of regulatory and compliance risks that could impact our business, financial condition, operating results and cash flows, including:~~ • Failure to comply with complex laws and regulations pertaining to government contracts and resources required for responding to related government inquiries. • Conditions associated with approvals and ongoing regulation of products may limit how and the extent to which we manufacture and market them. • Failure to comply with various health care laws could result in substantial penalties. • Failure to comply with obligations under USG pricing programs may require reimbursement for underpayments and the payment of substantial penalties, sanctions and fines. • The extent to which we may be able to lawfully offer to sell and sell unapproved products in many jurisdictions may be unclear or ambiguous and such activities may subject us to regulatory enforcement actions. ~~There are a number of competitive and political risks that could impact our business, financial condition, operating results and cash flows, including:~~ • Development and commercialization of pharmaceutical **products and our biologic** products are subject to evolving **competition from** private and public sector competition, **or biosimilar manufacturers**. • NARCAN ® (naloxone HCl) Nasal Spray is currently subject to generic and branded competition in the U.S. and may be subject to **additional** branded and generic competition in Canada. ~~In addition, the~~ **future success of NARCAN ® Nasal Spray, including in over-the-counter form, is subject to commercial availability of the product and our ability to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community.** • Biologic products may be affected by the approval and entry of follow-on biologics, or biosimilars in the United States and other jurisdictions. ~~There are a number of risks related to our intellectual property that could impact our business, financial condition, operating results and cash flows, including:~~ • Challenges in obtaining or maintaining intellectual property rights and defense or enforcement of such rights. • Potential discrepancies or challenges with respect to licenses, including our failure to comply with obligations under such licenses. • Potential loss or misappropriation of proprietary information, know-how, and trade secrets which carries the risk of reducing the value of our technology and products. • Entry of competing generic drugs upon **expiration of patent patents** and / or regulatory ~~expires~~ **exclusivity** or with patents no longer in force. ~~There are a number of risks related to reliance on third parties that could impact our business, financial condition, operating results and cash flows, including:~~ • The loss of sole-source suppliers or an increase in the price of inventory. • If other parties do not perform as contractually required or as expected, we may not be able to obtain regulatory approval for or commercialize our product candidates. ~~There are a number of legal and reputational risks that could impact our business, financial condition, operating results and cash flows, including:~~ • Unfavorable results of legal proceedings and government investigations could adversely impact our business, financial condition and results of operations. • Our work on PHTs has exposed us to criticism and may expose us to further criticism, from the media, government personnel and others, which could further harm our reputation, negatively affect our share price, operations and our ability to attract and retain talent. • Cybersecurity incidents involving us, our business partners, collaborators or other third parties could harm our ability to operate our business effectively in light of our heightened risk profile. • We could face product liability exposure associated with the use of our medical products. There can be no assurance that the SAFETY Act, Public Readiness and Emergency Preparedness Act (the "PREP Act"), or other liability protections will be sufficient to limit or avoid product liability, and defending such cases requires significant resources. ~~There are a number of financial risks that could impact our business, financial condition, operating results and cash flows, including:~~ • Our ability to maintain sufficient cash flow from our operations to pay our substantial debt, both now and in the future. • ~~Our ability to obtain additional funding~~ **Restrictions on the operation of our business** and **limitations on cash available for investment** ~~be able to raise capital when needed, including in~~ **our business operations** ~~order to be able to continue as a going concern~~ **result of our current indebtedness**. • Our ability to comply with the covenants under our Revolving Credit Facility,

Term Loan Facility, Senior Unsecured Notes and any other debt agreements to which we may be a party. • Our ability to remediate a material weakness in our internal control over financial reporting and to prepare accurate financial statements in a timely manner. There are a number of risks related to our strategic acquisitions, divestitures and collaborations that could impact our business, financial condition, operating results and cash flows, including: • We may not be successful in identifying, structuring or acquiring businesses and products to drive our growth. • Our failure to successfully integrate acquired businesses and / or assets into our operations and our ability to realize the benefits of such acquisitions. • Our failure to realize the full benefits from the sale of our **divestitures** ~~travel health business to Bavarian Nordic~~. There are a number of risks associated with our common stock, including, but not limited to: • Our business or our share price could be negatively affected as a result of the actions of stockholders. • The price of our common stock has been and remains subject to extreme volatility. The risk factors below contain more detailed descriptions of the risks identified above, as well as additional risks that may materially harm our business, financial condition or results of cash flows. GOVERNMENT CONTRACTING RISKS We currently derive, **and historically derived** a substantial portion of our revenue from USG procurement of the CYFENDUS ® vaccine and the TEMBEXA ®, oral antiviral and have historically derived a substantial portion of our revenue from USG procurement of the ACAM2000 ® vaccine, **VIGIV CNJ- 016 ®, BAT ®** and of / or BioThrax ®. If the USG' s demand for and / or funding for procurement of **these products** CYFENDUS ®, BioThrax ®, ACAM2000 ® and / or TEMBEXA ® are substantially reduced, our business, financial condition, operating results and cash flows would be materially harmed. We derive a substantial portion of our current and expected future revenues from USG procurement of CYFENDUS ®. ~~As with any approved product, there is a risk that we may encounter challenges causing delays or an inability to deliver CYFENDUS ®, which may have a material effect on our ability to generate and recognize revenue.~~ The success of our business and our future operating results are significantly dependent on anticipated funding for the procurement of our anthrax vaccines and the terms of such procurement by the USG, including the price per dose, the number of doses and the timing of deliveries. We have no certainty that funding will be made available for the procurement of our anthrax vaccines. If priorities for the Strategic National Stockpile (“ SNS ”) change generally, or as a result of the conclusion of the USG' s audit of the SNS, or with respect to the level of procurement of our anthrax vaccines, funding to procure future doses of CYFENDUS ® or BioThrax ® vaccines may be delayed, limited or not available, BARDA may never complete the anticipated full transition to stockpiling CYFENDUS ® in support of anthrax preparedness, and our future business, financial condition, operating results and cash flows could be materially harmed. In addition, ~~in the past we have derived~~ **derive** a substantial portion of our revenues from sales of ACAM2000 ® vaccine to the USG. ~~If~~ **In the past, the** priorities for of the SNS ~~have change~~ **changed** with respect to ACAM2000 ® vaccine **and if the priorities of the SNS change for ACAM ® vaccine in the future** or the USG decides not to exercise additional options under our ACAM2000 ® contract, our future business, financial condition, operating results and cash flows could be materially harmed. **As with any approved product, there is a risk that we may encounter challenges causing delays or an inability to deliver CYFENDUS ®, ACAM2000 ®, VIGIV CNJ- 016 ®, BAT ® and / or BioThrax ®, which may have a material effect on our ability to generate and recognize revenue.** Our USG procurement and development contracts require ongoing funding decisions by the USG. Any reduction or discontinuation of funding of any of these contracts could cause our business, financial condition, operating results and cash flows to suffer materially. The USG is the principal customer for our MCMs and the primary source of funds for the development of most of our product candidates in our development pipeline. We anticipate that the USG will also be a principal customer for any MCMs that we successfully develop from within our existing product development pipeline, as well as those we acquire in the future. Additionally, a significant portion of our revenue comes from USG development contracts and grants. Over its lifetime, a USG procurement or development program, such as for CYFENDUS ® under our development and procurement contract with BARDA, may be implemented through the award of many different individual contracts and subcontracts. The funding for such government programs is subject to Congressional appropriations, generally made on a fiscal year basis, even for programs designed to continue for several years. These appropriations can be subject to a number of uncertainties, including political considerations, changes in priorities due to global pandemics, the results of elections and stringent budgetary constraints. Additionally, our government- funded development contracts typically give the USG the right, exercisable in its sole discretion, to extend these contracts for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. On July 31, 2023, we were awarded a 10- year contract by BARDA for the advanced development, manufacturing scale- up, and procurement of Ebanga™ (ansuvimab- zyk) treatment for Ebola. The contract consists of a base period of performance with two option periods valued at approximately \$ 121 million, **which were exercised on September 5, 2024 and January 10, 2025, respectively,** and option periods for procurement of Ebanga™ over five years valued at up to \$ 583 million, **one of which was awarded in September 2024 (valued at \$ 41.9 million).** If all option periods are exercised, the total contract value will be valued at up to approximately \$ 704 million. If levels of government expenditures and authorizations for public health countermeasure preparedness decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the USG otherwise declines to exercise its options under this contract or our other existing contracts, our revenues would suffer, as well as our business, financial condition, operating results and cash flows. There can be no assurance that we will be able to secure follow- on product procurement contracts with the USG upon the expiration of any of our existing procurement contracts. A significant portion of our revenue is substantially dependent upon product procurement contracts with the USG and foreign governments for our MCMs and other commercialized products. Upon the expiration of a procurement contract, we may not be able to negotiate a follow- on procurement contract for the particular product on similar terms. We intend to negotiate follow- on procurement contracts for most of our MCMs and other commercialized products upon the expiration of a related procurement contract, but there can be no assurance that we will be successful obtaining any follow- on contracts. Even if we are successful in negotiating a follow- on procurement contract, it may be for a lower product volume, over a shorter period of performance or be on less

favorable pricing or other terms. An inability to secure follow-on procurement contracts for our approved products or product candidates could materially and adversely affect our revenues, and our business, financial condition, operating results and cash flows could be harmed. The government contracting process is typically a competitive bidding process and involves unique risks and requirements. Our business involves government contracts and grants, which may be awarded through competitive bidding. Competitive bidding for government contracts presents many risks and requirements, including: • the possibility that we may be ineligible to respond to a request for proposal; • the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals; • the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded; • the submission by third parties of protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and • in the event our competitors protest or challenge contract or grant awards made to us through competitive bidding, the potential that we may incur expenses or delays, and that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in the termination, reduction or modification of the awarded contract. The USG may choose not to award us future contracts for either the development of our new product candidates or for the procurement of our existing MCM and other commercialized products and may instead award such contracts to our competitors. **For example, ACAM2000 ® vaccine faces competition from JYNNEOSTM vaccine, which product has been procured by the USG in recent years.** If we are unable to secure particular contracts, we may not be able to operate in the market for products that are provided under those contracts. Additionally, if we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs or resources that we will be required to secure and, if applicable, perform under such contract awards, our growth strategy and our business, financial condition and operating results and cash flows could be materially and adversely affected. The amounts we are paid under our fixed price government procurement contracts are based on estimates we have made of the time, resources and expenses required for us to perform under those contracts. If our actual costs exceed our estimates, we may not be able to earn an adequate return or may incur a loss under these contracts, which could harm our operating results and materially reduce our net income. Our current procurement contracts with the U. S. Department of Health & Human Services (“HHS”) and the U. S. Department of Defense (“DoD”) are generally fixed price contracts. We expect that any future procurement contracts we successfully secure with the USG would likely also be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years, and when factoring in higher levels of inflation. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of such a contract or cause a loss, which could harm our operating results and materially reduce our net income. Unfavorable provisions in government contracts, some of which may be customary, may subject our business to material limitations, restrictions and uncertainties and may have a material adverse impact on our business, financial condition, operating results and cash flows. Government contracts customarily contain provisions that give the USG substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the USG to: • terminate existing contracts, in whole or in part, for any reason; • unilaterally reduce or modify contracts or subcontracts; • decline, in whole or in part, to exercise an option to purchase product under a procurement contract or to fund additional development under a development contract; • decline to renew a procurement contract; • claim certain rights to facilities or to products, including intellectual property, developed under the contract; • require repayment of contract funds spent on construction of facilities in the event of contract default; • take actions that result in a longer development timeline than expected; • direct the course of a development program in a manner not chosen by the government contractor; • suspend or debar the contractor from doing business with the government or a specific government agency; • pursue civil or criminal remedies under acts such as the False Claims Act and False Statements Act; and • control or prohibit the export of products. Generally, government contracts contain provisions permitting unilateral termination or modification, in whole or in part, at the USG’s convenience. Under general principles of government contracting law, if the USG terminates a contract for convenience, the government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the USG terminates a contract for default, the government contractor is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. All of our development and procurement contracts with the USG are terminable at their convenience with these potential consequences. In addition, our **contracts with the USG** grant the USG the right to use technologies developed by us under the government contract or the right to share data related to our technologies, for or on behalf of the USG. Under our **contracts with the USG**, we may not be able to limit third parties, including our competitors, from accessing certain of these technology or data rights, including intellectual property, in providing products and services to the USG. **MANUFACTURING RISKS** An inability to maintain manufacturing compliance at our manufacturing facilities, which could **damage our reputation and** adversely affect our business, financial condition, operating results and cash flows. The FDA conducts periodic inspections of our manufacturing facilities for compliance with CGMP requirements. The Company’s failure to maintain compliance with CGMP requirements at our manufacturing facilities has hindered and could continue to hinder our ability to continue manufacturing for our own products and for Bioservices customers, which could adversely affect our business, financial condition, operating results and cash flows. For example, in February 2022, the FDA inspected Emergent’s Camden facility located in Baltimore, Maryland and issued a Form FDA 483. In August 2022, the FDA issued a warning letter to Emergent related to the February 2022 inspection. The warning letter included issues pertaining to equipment cleaning and maintenance; aseptic sterilization technique and procedures; and quality systems. In July and August of 2023, the FDA inspected the Camden facility, and in October 2023, the FDA determined that the inspection classification of the Camden facility was “voluntary action indicated” or VAI. A VAI classification indicates that, although investigators found and documented objectionable conditions during the inspection, the

FDA would not take or recommend any administrative or regulatory action. Furthermore, the FDA concluded that the Camden facility inspection was "closed" under 21 CFR 20.64(d)(3) and issued to the Company a "Warning Letter close-out letter". In August 2023, the FDA inspected Emergent's Canton, Massachusetts facility located in Canton, Massachusetts and in issued a Form FDA 483. The Canton facility inspection was classified as VAI. In December 2023, the FDA inspected Emergent's Lansing, Michigan facility located in Lansing, Michigan and in each case the FDA issued a Form FDA 483 and both facilities were classified as "voluntary action indicated" or VAI. At this point a VAI classification indicates that, although investigators found and documented objectionable conditions during the Lansing inspection, the FDA would not take or recommend any administrative or regulatory action. In February 2024, the FDA inspected Emergent's Bayview facility in Baltimore, Maryland. The Bayview facility inspection was not classified as "no action indicated" or NAI aware of specific timing regarding the classification decision. The failure to remedy any remaining objectionable conditions at Emergent's manufacturing facilities, or any additional failures to maintain compliance with CGMP requirements at any of our manufacturing facilities, or any administrative or regulatory action or recommendation to take any such action by the FDA could damage our reputation and adversely affect our business, financial condition, operating results and cash flows. Disruption, damage to, destruction of, or any Disruption at, damage to or destruction of, our manufacturing facilities could impede our ability to manufacture anthrax vaccines, our ACAM2000 vaccine or our other products or product candidates, as well as impact the delivery of bioservices to third parties, which would harm our business, financial condition, operating results and cash flows. Any interruptions in our manufacturing operations could result in our inability to produce products and product candidates for delivery to satisfy the demands of our customers in a timely manner, which would reduce our revenues and materially harm our business, financial condition, operating results and cash flows. A number of factors could cause interruptions, including: • equipment malfunctions or failures; • technology malfunctions; • cyber-attacks; • work stoppages or slowdowns; • civil unrest and protests, including by animal rights activists; • injunctions; • damage to or destruction of our manufacturing equipment, or of one or more of our facilities; • findings and recommendations of health authorities or qualified persons in connection with facility inspections; • ongoing supply chain interruptions; and • product contamination or tampering. The factors listed above could cause disruptions at any of our manufacturing facilities. We do not have any redundant manufacturing facilities for any of our products. Accordingly, any damage to, or destruction of, or disruption at or destruction of one or more of our facilities could impede our ability to manufacture our products, and our product candidates and our ability to provide manufacturing and development services for external customers, result in losses and delays, including delays in the performance of our contractual obligations or delays in our clinical trials, any of which could be costly to us and materially harm our business, financial condition, operating results and cash flows. Providers of MCMs could be subject to an increased risk of terrorist activities. The USG has designated our Lansing, Michigan facility as requiring additional security. Although we continually evaluate and update security measures, there can be no assurance that any additional security measures would protect these facilities from terrorist efforts determined to disrupt our manufacturing activities. Problems may arise during the production of our products and product candidates, as well as those we produce for our Bioservices customers, due to the complexity of the processes involved in their product development, manufacturing and shipment or other factors. Significant delays in product development or manufacturing and our ability to ramp up production to meet the needs of our customers could cause delays in recognizing revenues, which would harm our business, financial condition, operating results and cash flows. The majority of our products and product candidates are biologics. Manufacturing biologics, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly-defined manufacturing process. Problems during manufacturing may arise for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. Slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, contamination including from particulates among other things, filtration, filling, labeling, packaging, storage and shipping, potency and stability issues and other quality control testing, may result in lot failures or manufacturing shut-downs, delays in the release of lots, product recalls, spoilage or regulatory action. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, as our equipment ages, it will need to be replaced, which has the potential to result in similar consequences. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time, we may experience deviations in the manufacturing process, including as a result of regulatory action, that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation, or other restrictions on the marketing or manufacturing of a product, any of which could be costly to us, damage our reputation and negatively impact our business. Regulatory action, including the issuance of Form FDA 483s and warning letters can also have an impact. Additionally, if changes are made to the manufacturing process, we may be required to provide the FDA with pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of any impacted products before and after the changes. We are contractually required to ship our biologic products at a prescribed temperature range and variations from that temperature range could result in loss of product and could significantly and adversely impact our revenues, which would harm our business, financial condition, operating results and cash flows. In addition, we may not be able to ramp up our manufacturing processes to meet the rapidly changing demand or specifications of our customers on the desired timeframe, if at all. Our inability to ramp up manufacturing to meet the demand or specifications of our customers or the inability to timely obtain regulatory authorization to produce the products or product candidates of our customers could also harm our business, financial condition, operating results and cash flows. Our products and product candidates procured by the USG and other customers require us to perform tests for and meet certain product potency and lot-release standards prescribed by the FDA and other agencies, which may not be met on a timely basis or at all. We are unable to sell any products and product candidates that

fail to satisfy certain testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before certain lots are released for sale. Potency testing of each applicable lot is performed against qualified control lots that we maintain. We continually monitor the status of such reference lots for FDA compliance and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are unable to satisfy **regulatory authority and / or** USG requirements for the release of our products or product candidates, our ability to supply such products and product candidates to authorized buyers would be impaired until such time as we become able to meet such requirements, which could materially harm our future business, financial condition, operating results and cash flows. Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities. Our operations involve the use of hazardous materials, including chemicals, bacteria and viruses, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select Agent Program, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register with and be inspected by the Centers for Disease Control and Prevention (the "CDC") and the Animal and Plant Health Inspection Service if we have in our possession, or if we use or transfer, select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires stringent safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of registered entities. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations in this area can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials. From time to time, we have been involved in remediation activities and may be so involved in the future. Any related cost or liability might not be fully covered by insurance, could exceed our resources and could have a material adverse effect on our business, financial condition, operating results and cash flows. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS, U. S. Department of Agriculture and the DoD, as well as regulatory authorities in Canada.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS The product candidates that we work on **internally or for our Bioservices third-party** customers may not be safe or effective and even if they are, we may be unable to manufacture sufficient quantities to meet demand. We provide bioservices for the development and / or manufacture of various product candidates. There can be no assurance that these product candidates will be safe or effective or that they will be authorized for emergency use or approved by the FDA or any other health regulatory authority. Even if product candidates are found to be safe and / or effective and receive authorization or approval by a health regulatory authority or we receive authorization to produce drug substance or drug product at our facilities, the manufacturing processes for our Bioservices programs are complex. There can be no assurance that we will be able to produce sufficient clinical or commercial quantities of any product candidate in a timely basis or at all. Difficulties manufacturing COVID- 19 product candidates for certain Bioservices customers and the November 2021 termination of the ~~termination of the~~ Center for Innovation in Advanced Development and Manufacturing agreement with BARDA for COVID- 19 vaccine development and manufacturing caused us to suffer considerable reputational and financial damage and resulted in the ~~instigation-~~ **initiation** of stockholder litigation and government investigations described elsewhere in this Annual Report. **In June 2022, we became involved in a contractual dispute with Janssen regarding the manufacture of its COVID- 19 vaccine, which resulted in arbitration proceedings. See Note 19, "Litigation " in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10- K for more detail. While the dispute initially created additional financial and operational uncertainty, the matter was resolved in July 2024. Pursuant to the Settlement Agreement, the Company received \$ 50. 0 million from Janssen, and all claims among the parties arising from the Janssen Agreement were resolved; however, the dispute, litigation, the associated cost and reputational harm have had a material adverse effect on our business.** Further, ~~as our announcement in the third quarter of 2023 that we have reduced the emphasis are de-emphasizing focus~~ **on our Bioservices business, may raise concerns may exist** regarding our ability to fulfill manufacturing commitments to our Bioservices customers. Any future failure to satisfy manufacturing commitments could adversely affect our reputation, subject us to potential legal liability and harm our business, financial condition, operating results and cash flows. Our growth depends on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates or experience significant delays or unanticipated costs in doing so, our business would be materially and adversely affected. We have invested significant efforts and financial resources in the development of our vaccines, therapeutics and medical device product candidates and the acquisition of additional product candidates. In addition to our product sales, our ability to generate revenue is dependent on a number of factors, including the success of our development programs, the USG' s interest in providing development funding for or procuring certain of our product candidates, and the commercial viability of our acquired or developed product candidates. The commercial success of our product candidates can depend on many factors, including accomplishing the following in an economical manner: • successful development, formulation and CGMP or Quality System Regulation (" QSR") scale- up of manufacturing that meets FDA and / or foreign regulatory requirements; • successful program partnering; • successful completion of clinical or non- clinical development; • receipt of marketing approvals, clearances, or other authorizations from the FDA and equivalent foreign regulatory authorities; • establishment of commercial manufacturing processes and product supply arrangements; • training of a commercial sales force for the product; • successful registration and maintenance of relevant patent and / or other proprietary protection; • competitive pricing and market access; and • acceptance of the product by

potential government and other customers. In particular, the success of NARCAN® (naloxone HCl) Nasal Spray, including in over-the-counter form, is subject to commercial availability of the product and our ability to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable products. Failure to obtain regulatory approval for product candidates, particularly in the United States, could materially and adversely affect our financial resources, which would adversely affect our business, financial condition, operating results and cash flows. Before obtaining regulatory approval or other authorization of our product candidates, we and our collaborative partners, where applicable, must conduct pre-clinical studies and clinical trials to establish proof of concept and demonstrate the safety and efficacy of our product candidates. Pre-clinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of such trials do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing. We may experience unforeseen events or issues during, or as a result of, pre-clinical testing, clinical trials or animal efficacy studies. These issues and events, which could delay or prevent our ability to receive regulatory approval for a product candidate, include, among others: • our inability to manufacture sufficient quantities for use in trials; • the unavailability or variability in the number and types of subjects for each study; • safety issues or inconclusive or incomplete testing, trial or study results; • drug immunogenicity; • lack of efficacy of product candidates during trials; • government or regulatory restrictions or delays; and • greater than anticipated costs of trials. Pre-clinical and clinical testing for certain of our MCM product candidates may face additional difficulties and uncertainties because they cannot ethically or feasibly be tested in human subjects. In the U.S. we expect to rely on the Animal Rule to obtain regulatory approval for some of our MCM product candidates. The Animal Rule permits, for certain limited diseases and circumstances, the use of animal efficacy studies, together with human clinical safety and immunogenicity trials, to support an application for marketing approval. For a product approved under the Animal Rule, certain additional post-marketing requirements apply. For example, to the extent feasible and ethical, applicants must conduct post-marketing clinical studies, such as field studies in the event of an outbreak or act of bioterrorism, to assess the drug's safety and effectiveness. It is possible that results from the animal efficacy studies used to support approval under the Animal Rule may not be predictive of the actual efficacy of our product candidates in humans. Under the Public Health Service Act (the "PHSA") and the Federal Food, Drug, and Cosmetic Act (the "FDCA"), the Secretary of HHS can contract to purchase MCMs for the SNS prior to FDA approval, clearance, or other authorization of certain MCM product candidates. If the USG does not provide funding for and procure our MCM product candidates, they generally will have to be approved by the FDA through traditional regulatory mechanisms prior to sale and distribution in the United States. We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates. We continue to evaluate our product development strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates.

We As part of our stabilization efforts in 2024 related to our multi-year strategic plan, we changed and refocused several areas of our business, and may continue to change or refocus our existing business activities, including product development, commercialization and manufacturing activities based on government funding decisions and other factors. This could required changes, and may require changes in the future, in our facilities and our personnel. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates or choose candidates for which government development funds are not available. Our decisions to allocate our R & D, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better business opportunities. Similarly, our decisions to delay or terminate product development programs could also cause us to miss valuable opportunities.

REGULATORY AND COMPLIANCE RISKS There are a number of complex laws and regulations that pertain to government contracts and compliance with those laws and regulations require significant time and cost, which could have a material adverse effect on our business, financial condition, operating results and cash flows. As a manufacturer and supplier of MCMs and other approved products to the USG addressing PHTs, we must comply with numerous laws and regulations relating to the procurement, formation, administration and performance of government contracts. These laws and regulations govern how we **operate our business and transact business with our government clients and impose compliance costs on our operations. In addition, in some instances these laws and regulations may be subject to sudden change, which may impose additional costs and related obligations on our operations or require us to make changes to the way we operate our business or transact business with our government clients.** For a detailed description of the most significant regulations that affect our government contracting business, see the prior discussion under "Regulation- Government Contracting." We may be subject to government investigations of compliance with government acquisition regulations. USG agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. Even though we take significant precautions to identify, prevent and deter fraud, misconduct and non-compliance, we face the risk that our personnel or outside partners may engage in misconduct, fraud or improper activities. If we are audited or investigated and such audit or investigation were to uncover improper or illegal activities, we could be subject to civil and criminal fines and penalties, administrative sanctions, including suspension or debarment from government contracting, and suffer significant reputational harm. The loss of our status as an eligible government contractor or significant fines or penalties associated with contract non-compliance or resulting from investigations could have a material adverse effect on our business. Our long-term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize product candidates we develop or acquire and, if we are not successful, our business, financial condition, operating results and cash flows may suffer. Our product candidates and the activities associated with them are subject to

extensive FDA regulation and oversight. This includes, but is not limited to, laws and regulations governing product development, product labeling, product testing, manufacturing, storage, product distribution, record keeping, and advertising and promotion. In limited circumstances, governments may have the authority to procure products that have not obtained regulatory approval to stockpile for emergency preparedness and to respond to public health emergencies. In other circumstances, failure to obtain regulatory approval for a product candidate will prevent us from selling and commercializing the product candidate. In the United States, to obtain authorization from the FDA to market and sell any of our future drug, biologic, or vaccine products, we will be required to submit a New Drug Application (an “NDA”) or Biologics License Application (a “BLA”) to the FDA. Under the FDCA, the PHSA, and the FDA’s implementation of those statutes, a company must support an NDA or BLA with substantial evidence that the product candidate is effective and evidence that the product is safe. Ordinarily, the FDA requires data from adequate and well- controlled clinical trials, including Phase 3 trials conducted in patients with the disease or condition being targeted, to demonstrate that a drug meets the statutory standards for approval. Once an NDA or BLA is submitted, the FDA has substantial discretion and may refuse to accept our application or may decide that our data are insufficient to support approval and require additional pre- clinical, clinical or other studies. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, or to conditions of approval, or contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the product. Likewise, the data in our device submissions may be insufficient to support approval, de novo classification or clearance where required, and we may not be able to demonstrate to the satisfaction of the FDA that our devices are safe or effective for their intended uses or, for a 510 (k) device, that they are substantially equivalent to the predicate. Even if we are granted 510 (k) clearances, de novo authorizations, or premarket approval application (“PMA”) approvals, they may include significant limitations on the indications for use for the device. ~~Before we can market a new medical device, or an existing medical device for a new use, or make significant modifications to an existing product, we must first receive either clearance under Section 510 (k) of the FDCA, de novo authorization, or approval of a PMA from the FDA, unless an exemption applies. These marketing submissions must also be supported by appropriate data, including in many cases clinical data.~~ Likewise, changes to our combination products, including changes to the device constituent part, may also require a new submission to, and approval from, the FDA. ~~However~~ **The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and approved by necessary government agencies, which could adversely affect our business. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.** Our MCM product candidates may be eligible for approval under the FDA’s “Animal Rule,” under which findings from adequate and well controlled animal efficacy studies may serve as the basis of an approval when it is not feasible or ethical to conduct efficacy trials in humans. We cannot guarantee that the FDA will permit us to proceed with approval or licensure of any of our MCM product candidates under the Animal Rule. Even if we are able to proceed under the Animal Rule, product development can take a considerable amount of time, and the FDA may decide that our data are insufficient to support approval and require additional pre- clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Furthermore, products approved under the Animal Rule are subject to certain additional post- marketing requirements. We cannot guarantee that we will be able to meet this regulatory requirement even if one or more of our product candidates are approved under the Animal Rule. The process of obtaining these regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process may cause delays in the approval or other marketing authorization, or rejection of an application. There is a high rate of failure inherent in the medical product development process, and product candidates that appear promising at early stages of development may fail for a number of reasons, and positive results from pre- clinical studies may not be predictive of similar results in human clinical trials. Similarly, promising results from earlier clinical trials of a product candidate may not be replicated in later clinical trials. Failure to successfully develop future product candidates may materially adversely affect our business, financial condition, operating results and cash flows. Unapproved and investigational stage products are also subject to the FDA’s laws and regulations governing advertising and promotion, which prohibit the promotion of both unapproved products and unapproved uses of approved products. There is some risk that the FDA could conclude that our communications relating to unapproved products or unapproved uses of approved products constitute the promotion of an unapproved product or product use in violation of FDA laws and regulations. There is also a risk that a regulatory authority in another country could take a similar position under that country’s laws and regulations and conclude that we have violated the laws and regulations related to product development, approval, or promotion in that country. If the FDA or any foreign regulatory authority determines that any of our communications constitute pre- approval promotion or promotion of an off- label use, the FDA could request that we modify our promotional materials, issue an untitled letter or warning letter, or subject us to regulatory or enforcement actions, including injunction, seizure, civil fine or criminal penalties. Even if we or our collaborators obtain marketing approvals for our product candidates, the conditions of approvals and ongoing regulation of our products may limit how we manufacture, market and sell our products, which could materially impair our ability to generate revenue. Once marketing authorization has been granted, we and our business partners will remain subject to ongoing regulatory oversight of our medical products, including with respect to labeling; safety surveillance and reporting; registration and listing requirements; CGMP and QSR requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents; advertising and promotional activities; requirements regarding the distribution of samples to physicians

and related recordkeeping; and medical device design, development and manufacturing. The FDA and other agencies, including the U. S. Department of Justice (“ DOJ ”) and the HHS Office of Inspector General (“ OIG ”), closely regulate and monitor the marketing and promotion of medical products to ensure that they are marketed in a manner consistent with the FDA- approved label. For drug products, we must promote the product in a manner consistent with the full prescribing information or, for 510 (k) cleared devices, consistent with the cleared indication. The FDA, DOJ, and OIG impose stringent restrictions on manufacturers’ communications regarding unapproved / uncleared products and unapproved / uncleared uses of approved / cleared products. If we market unapproved / uncleared products or market our approved / cleared products for unapproved / uncleared indications, we may be subject to enforcement action. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. Certain of our products are subject to post- marketing requirements (“ PMRs ”), which we are required to conduct, and post marketing commitments, which we have agreed to conduct. The FDA has the authority to take action against sponsors who fail to meet the obligations of a PMR, including civil monetary penalties and / or misbranding charges. In addition, discovery of previously unknown adverse events or other problems with our products, manufacturing partners or manufacturing processes, or failure to comply with regulatory requirements, may result in various penalties and sanctions. For all FDA- regulated products, if the FDA finds that a manufacturer has failed to comply with applicable laws and regulations, or that a product is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and other remedies, including but not limited to: • restrictions on such products, manufacturers or manufacturing processes; • restrictions on the labeling or marketing of a product; • restrictions on distribution or use of a product; • requirements to conduct post- marketing studies or clinical trials; • warning letters or untitled letters; • refusal to approve pending applications or supplements to approved applications that are submitted; • delay in or refusal to approve, clear or authorize pending PMA applications, 510 (k) premarket submissions, or de novo authorization requests; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our products; • product seizure; and • injunctions or the imposition of civil or criminal penalties. If we and our collaborators are not able to comply with post- approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market and sell any products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. Any product candidate for which we or our collaborators obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved. Likewise, non-compliance with EU **, any EU Member State, or UK** requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the **EU European** and other legal and regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Non- compliance with similar requirements in other foreign jurisdictions can also result in enforcement actions and significant penalties. Current and future **policy or** legislation may increase the difficulty and cost for us and **any our** collaborators to obtain marketing approval of and commercialize our product candidates **and, which** may affect the prices we, or our collaborators, may obtain. In the United States and foreign jurisdictions, there have been a number of **policy,** legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any **approved product products candidates for which we obtain marketing approval**. We expect that current laws, as well as other health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or any collaborators, may receive for any approved products. ~~Additionally, there~~ **There** has been ~~recent~~ **continued** heightened federal governmental scrutiny over the manner in which manufacturers set prices for their marketed products. **This includes** ~~For example, there have been several recent~~ Congressional inquiries and ~~has been~~ proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Further, the Inflation Reduction Act of 2022 (the “ IRA ”), was signed into law on August 16, 2022. While the IRA is still subject to rulemaking (~~with more information to come via~~ **and currently is being implemented through** guidance documents from the responsible federal agencies), the IRA, as written, ~~will,~~ among other changes, ~~give~~ **gives** HHS the ability and authority to directly negotiate with manufacturers the price that Medicare will pay for certain high- priced drugs. The IRA ~~will also require~~ **requires** manufacturers of certain Part B and Part D drugs to issue to HHS rebates based on certain calculations and triggers (i. e., when drug prices increase and outpace the rate of inflation). ~~At~~ **While we are not directly affected by the IRA at** this time, ~~we cannot predict the implications the IRA provisions will have on our business. These~~ **these** types of laws may have a significant impact on our ability to set a product price we believe is fair and may adversely affect our ability to generate revenue and achieve or maintain profitability. **A number of** ~~Additionally, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program (“ SIP ”), to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation. At least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada, and at least three states (Colorado, Florida, and New Mexico) have submitted SIPs to the FDA for review and approval. At the state level, individual states are increasingly aggressive in passing legislation and implementing~~ **implemented** regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to

encourage importation from other countries and bulk purchasing. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, and wholesale distributors, to disclose information about pricing of pharmaceuticals. ~~In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. A growing number of state attorneys general are filing legal challenges, including antitrust challenges, related to drug pricing and reimbursement against various supply chain entities, such as pharmacy benefit managers, and such litigation may also involve drug manufacturers in the future.~~ These measures could reduce the ultimate demand for ~~our approved~~ products, ~~once approved~~, or put pressure on our product pricing. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for our ~~product candidates~~ **product candidates** or additional pricing pressures. If we fail to comply with foreign, federal, state and local health care laws, including fraud and abuse laws, health information privacy and security laws, and antitrust laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. In the United States, certain of our products are reimbursed under federal and state health care programs such as Medicaid, Medicare, Tricare, and / or state pharmaceutical assistance programs. Many foreign countries have similar laws. Federal and state laws designed to prevent fraud and abuse under these programs prohibit pharmaceutical companies from offering valuable items or services to customers or potential customers to induce them to buy, prescribe, or recommend our product (the so- called “ anti- kickback ” laws). Exceptions are provided for discounts and certain other arrangements if specified requirements are met. Other federal and state laws, and similar foreign laws, not only prohibit us from submitting any false information to government reimbursement programs but also prohibit us, our employees, or any third party acting on our behalf from doing anything to cause, assist, or encourage our customers to submit false claims for payment to these programs. We are also subject to various federal, state and foreign antitrust and competition laws that prohibit certain activities that may have an impact against potential competitors. Violations of the various fraud and abuse and antitrust laws may result in severe penalties against the responsible employees and us, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Some of the laws that may affect our ability to operate include:

- the federal Anti- Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, to induce, or in return for, either the referral of an individual, or the purchase, lease, prescribing or recommendation of an item, good, facility or service reimbursable by a federally funded health care program, such as the Medicare or Medicaid program. The term “ remuneration ” has been interpreted broadly and may constrain our marketing practices, educational programs, pricing policies and relationships with health care providers or other entities, among other activities;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal health care program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability, including mandatory treble damages and significant per- claim penalties.
- the U. S. federal Health Insurance Portability and Accountability Act of 1996 (“ HIPAA”), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, health care benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy, security and transmission of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA’ s security standards directly applicable to “ business associates, ” or independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- the Physician Payments Sunshine Act and its implementing regulations require certain manufacturers of drugs, biologics, medical devices and medical supplies for which payment is available under Medicare, Medicaid or the Children’ s Health Insurance Program to report certain payments and transfers of value made to U. S. physicians, prescribers and teaching hospitals, as well as ownership or investment interests held by physicians, and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws, which may apply to items or services reimbursed by any third- party payor, including commercial insurers; state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; state, local and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’ s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, obtain pharmaceutical agent licensure, and / or otherwise restrict payments that may be made to health care providers and entities; and state, local and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to health care providers or entities, or marketing expenditures. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the federal Anti- Kickback Statute, it is possible that some of our business activities could be subject to challenges under one or more of such laws. If our operations are found to be in violation of any of the laws described above or otherwise, we may be subject to penalties, including civil and criminal

penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from federal health care programs and the curtailment or restructuring of our operations. Any such penalties could adversely affect our financial results. We continue to improve our corporate compliance program designed to ensure that our development, marketing, and sales of existing and future products and product candidates are in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Efforts to ensure that our business arrangements with third parties comply with health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from government funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If a third party fails to comply with applicable laws and regulations while acting on our behalf, we may also be subject to criminal, civil, and administrative penalties, including those listed above. The United States government, state governments and private payors regularly investigate the pricing and competitive practices of pharmaceutical companies and biotechnology companies, and many file actions alleging that inaccurate reporting of prices has improperly inflated reimbursement rates. We may also be subject to investigations related to our pricing practices. Regardless of merit or eventual outcome, these types of investigations and related litigation can result in: • diversion of management time and attention; • significant legal fees and payment of damages or penalties; • limitations on our ability to continue certain operations; • decreased product demand; and • injury to our reputation. Moreover, an adverse outcome, or the imposition of penalties or sanctions for failing to comply with applicable fraud and abuse and antitrust laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. If we fail to comply with our obligations under U. S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid rebate program will continue to increase our costs and the complexity of compliance and will be time- consuming. Because we participate in the Medicaid rebate program, we are required to report average sales price (" ASP"), information to CMS for certain categories of drugs that are paid for under Part B of the Medicare program. Future statutory or regulatory changes or CMS binding guidance could affect the ASP calculations for our products and the resulting Medicare payment rate and could negatively impact our results of operations. Pricing and rebate calculations vary among products and programs, involve complex calculations and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current AMP and " best price " for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. Such restatements and recalculations would increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Price recalculations also may affect the " ceiling price " at which we are required to offer our products to certain covered entities, such as safety- net providers, under the 340B / Public Health Service (" PHS") drug pricing program. In addition, if we are found to have made a misrepresentation in the reporting of ASP, we are subject to civil monetary penalties for each such price misrepresentation and for each day in which such price misrepresentation was applied. If we are found to have knowingly submitted false AMP or " best price " information to the government, we may be liable for civil monetary penalties per item of false information. Any refusal of a request for information or knowing provision of false information in connection with an AMP survey verification would also subject us to civil monetary penalties. In addition, our failure to submit monthly / quarterly AMP or " best price " information on a timely basis could result in a civil monetary penalty per day for each day the information is late beyond the due date. Such failure could also be grounds for CMS to terminate our Medicaid drug rebate agreement, under which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot ensure that our submissions will not be found by CMS to be incomplete or incorrect. In order for our products to be reimbursed by the primary federal governmental programs, we must report certain pricing data to the USG. Compliance with reporting and other requirements of these federal programs is a pre- condition to: (i) the availability of federal funds to pay for our products under Medicaid and Medicare Part B; and (ii) procurement of our products by the Department of Veterans Affairs (" DVA"), and by covered entities under the 340B / PHS program. The pricing data reported are used as the basis for establishing Federal Supply Schedule (" FSS"), and 340B / PHS program contract pricing and payment and rebate rates under the Medicare Part B and Medicaid programs, respectively. Pharmaceutical companies have been prosecuted under federal and state false claims laws for submitting inaccurate and / or incomplete pricing information to the government that resulted in increased payments made by these programs. Although we maintain and follow strict procedures to ensure the maximum possible integrity for our federal pricing calculations, the process for making the required calculations is complex, involves some subjective judgments and the risk of errors always exists, which creates the potential for exposure under the false claims laws. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, and our methodologies for calculating federal prices are found to include flaws or to have been incorrectly applied, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a

material adverse effect on our business, financial condition and results of operations. To be eligible to have our products paid for or reimbursed with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also must participate in the DVA FSS pricing program. To participate, we are required to enter into an FSS contract with the DVA, under which we must make our innovator “covered drugs” available to all federal purchasers. In addition, for the “Big Four” federal agencies — the DVA, the DoD, the PHS (including the Indian Health Service), and the Coast Guard — we must make covered drugs available at pricing that is capped at the statutory federal ceiling price (“FCP”). The FCP is calculated using the formula set forth in Section 603 of the Veterans Health Care Act of 1992 (the “VHCA”) and based on a weighted average wholesale price known as the Non-Federal Average Manufacturer Price (“Non-FAMP”), which manufacturers are required to report on a quarterly and annual basis to the DVA. Under the VHCA, knowingly providing false information in connection with a Non-FAMP filing can subject us to significant penalties for each item of false information. If we overcharge the government in connection with our FSS contract or Tricare program agreements, whether due to a misstated FCP or otherwise, we are required to disclose the error and refund the difference to the government. The failure to make necessary disclosures and / or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, can be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. From time to time, we sell unapproved MCMs to government entities under certain circumstances. While this is permissible in some cases, the extent to which we may be able to lawfully offer to sell and sell unapproved products in many jurisdictions may be unclear or ambiguous. Such sales could subject us to regulatory enforcement action, product liability and reputational risk. Under certain and narrow circumstances, MCMs may be procured by government entities prior to approval by the FDA or other U. S. regulatory authorities, a practice which we follow followed in connection with certain MCMs, including TROBIGARD® (and CYFENDUS®), prior to its approval by the FDA in the United States. In the United States, the Secretary of HHS has the authority to contract to purchase MCMs for the SNS prior to FDA approval of the relevant MCM in specified circumstances. The FDA also has the authority to permit the emergency use of medical products that have not yet been approved by the FDA under an EUA. An EUA terminates when the EUA is revoked or the emergency declaration underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, clearance, or other marketing authorization for a product. An EUA has not been granted for TROBIGARD®. Absent an applicable exception, our MCM product candidates generally will have to be approved, licensed, or cleared by the FDA or other regulatory authorities in the relevant country through traditional pathways before we can sell those products to governments. Additionally, the laws in certain jurisdictions regarding the ability of government entities to purchase unapproved product candidates can be ambiguous, and the permissibility of exporting unapproved products from the United States and importing them to foreign countries may be unclear in some instances. Nevertheless, government bodies, such as U. S. federal entities other than HHS, state and local governments within the United States, and foreign governments have sought and may further seek to procure our MCM product candidates that are not yet approved. In this situation, we would expect to assess the permissibility and liability implications of supplying our product candidates to such entities on a case-by-case basis, which presents certain challenges, both in the case of U. S. and foreign governments, and particularly under emergency conditions. In addition, agencies or branches of one country’s government may take different positions regarding the permissibility of such sales than another country’s government or even other agencies or branches of the same government. If local enforcement authorities disagree with our conclusion that such activities are permissible, they may take enforcement action against us. In addition, the sale of unapproved products also could give rise to product liability claims for which we may not be able to obtain adequate indemnification or insurance coverage. For example, despite liability protections applicable to claims arising under U. S. law and resulting from the use of certain unlicensed or unauthorized MCMs, such as a declaration issued under the PREP Act, plaintiffs still may bring lawsuits alleging, among other things, that their claims are not barred under the PREP Act. In the event that a user of one or more of our products experiences an adverse event, we may be subject to additional reputational risk if the product has not been approved by the FDA or the corresponding regulatory authority of another country, particularly because we will not have approved labeling regarding the safety or efficacy of those products. In addition, legislatures and other governmental bodies that have oversight responsibility for procuring agencies may raise concerns after the fact, even if procurement was permissible at the time, which could result in negative publicity, reputational risk and harm to our business prospects. There is also a risk that our communications with governments about our unapproved / uncleared products, such as in the procurement context, could be considered promotion of an unapproved / uncleared product or unapproved / uncleared use of an approved product. Therefore, there is a risk that we could be subject to enforcement actions if found to be in violation of such laws or regulations. Even after regulatory approval is received, if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions, penalties or withdrawal from the market. Any vaccine, therapeutic product or medical device for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to the continual requirements of and review by the FDA and other regulatory bodies. Our approved products are subject to these requirements and ongoing review. For drugs and vaccines, these requirements include submissions of safety and other post-marketing information and reports, plasma donor testing, registration requirements, CGMP, requirements relating to potency and stability, quality control, quality assurance, restrictions on advertising and promotion, import and export restrictions and recordkeeping requirements. Requirements for medical devices are similar and include QSR compliance, establishment registration and device listing; record keeping; restrictions on advertising and promotion; post-market surveillance, and restrictions on import and export. In addition, various state laws require that companies that manufacture and / or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Some states have similar requirements for devices. Because of the breadth of these laws, it is possible that some of our business activities could be subject

to challenge under one or more of such laws. Government regulators enforce CGMP, QSR, and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic and foreign manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our domestic and foreign facilities where products offered and sold in Canada are produced, or related formulation and filling operations are conducted. The FDA, Health Canada, and other foreign regulatory agencies conduct periodic inspections of our facilities. Following several of these inspections, regulatory authorities have issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, regulatory authorities find that we are not in substantial compliance with all applicable requirements, or if they are not satisfied with the corrective actions we take, our regulators may undertake enforcement action against us, which may include: • warning letters, untitled letters, and other communications; • product seizure or withdrawal of the product from the market; • restrictions on the marketing or manufacturing of a product; • suspension or withdrawal of regulatory approvals or refusal to approve pending applications or other marketing submissions, or supplements to approved applications; • fines or disgorgement of profits or revenue; and Similar action may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. For instance, our products are tested regularly to determine if they satisfy potency and stability requirements for their required shelf lives. Failure to meet potency, stability or other specification requirements could result in delays in distributions, recalls or other consequences. In November 2022, three lots of our RSDL ® kits ~~was~~ **were** recalled due to leakage (the "November 2022 Recall"), which could cause the product not to perform as effectively as intended. We identified and remediated the cause leading to the November 2022 Recall, as well as completed all required actions, notices and report submissions related to the recalled batch. **The FDA terminated** ~~We are currently awaiting formal closure of~~ **the November 2022 Recall in October 2024 from the FDA, Center for Devices and Radiological Health.** Even if regulatory approval, clearance, or other marketing authorization of a product is granted, the approval, clearance, or marketing authorization may be subject to limitations on the indicated uses for which the product may be marketed or sold or to the conditions of approval. Regulatory approval or other authorization may also contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the product. If we experience any of these post- approval events, our business, financial condition, operating results and cash flows could be materially and adversely affected. Additionally, companies may not promote unapproved products or unapproved uses of approved products (i. e., " off- label " uses or uses that are not described in the product ' s approved labeling and / or that differ from the uses approved or cleared by the applicable regulatory agencies). A company that is found to have improperly promoted an unapproved / uncleared product or an unapproved / uncleared use of an approved / cleared product may be subject to significant liability, including civil and administrative remedies (such as entering into corporate integrity agreements with the USG), as well as criminal sanctions. If our employees or agents engage in marketing of an unapproved / uncleared product or the unapproved / uncleared use of an approved / cleared product, we could be subject to civil or criminal investigations and monetary and injunctive penalties, which could adversely impact our ability to conduct business in certain markets, negatively affect our business, financial condition, operating results and cash flows, and damage our reputation. Failure to obtain or maintain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could limit the growth of our business. We currently sell certain of our products outside the United States and intend to expand the countries in which we sell our products ~~and~~. **We currently** ~~have received~~ **market authorization under the mutual recognition procedure to sell BioThrax ® in France , Italy, the Netherlands, Poland, and Germany the United Kingdom.** To market or sell our products in foreign jurisdictions under normal circumstances, we generally need to obtain separate regulatory approvals and comply with numerous and varying requirements or use alternative " emergency use " or other exemptions from general approval and import requirements. Approval by the FDA in the United States **, in Canada by Health Canada,** or the mutual recognition procedure in the European member states does not ensure approval by all foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review beyond that required by the FDA or under the mutual recognition procedure. There is also a risk that a regulatory authority in another country could conclude that we have violated the rules and regulations related to product development, approval or promotion in that country. Therefore, there is a risk that we could be subject to a foreign enforcement action if found to be in violation of such laws and regulations. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and we may be unable to successfully commercialize our products in desired jurisdictions internationally if no alternate procurement pathway is identified for authorized government customers in a particular jurisdiction. We have limited experience in preparing, filing and prosecuting the applications necessary to gain foreign regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process. Our reliance on third parties can introduce additional uncertainty into the process. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency (the " MHRA ") ~~, became responsible for supervising~~ **serves as the regulatory authority overseeing** medicines and medical devices in Great Britain ~~(, comprising England, Scotland , and Wales) under domestic law, whereas while~~ Northern Ireland **is** ~~continues to be~~ **subject to EU regulations** ~~European Union rules~~ **under the Windsor Framework (replacing the Northern Ireland Protocol in February 2023).** ~~The~~ **As of January 1, 2025, the MHRA relies on** ~~will assume full regulatory oversight for all medicinal products in~~ **the Human UK, including Northern Ireland, and the European Medicines Agency Regulations 2012- (SI 2012 / 1916) (as amended) (the " HMR-EMA ") , as the basis** ~~will no longer have a role in approving products for regulating medicines~~ **the Northern Ireland market. Additionally, a new International Recognition Procedure (" IRP") took effect on January 1, 2024, designed to facilitate marketing authorizations in the UK for products already approved by a recognized regulatory authority . The HMR has incorporated into** ~~IRP applies to products authorized by the domestic law of~~ **EMA (for EU centralized approvals), national regulators in** ~~the body of European Union law instruments governing medicinal products that pre~~ **Economic Area (" EEA"), and the U. S. Food and Drug Administration (" FDA"),**

among others. However, reliance existed prior to the United Kingdom's withdrawal from the European Union **based or recognition- based regulatory decisions are not eligible under this procedure**. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom **or elsewhere** for our product candidates, which could significantly and materially harm our business. **In addition, due the evolving nature of UK regulations, further divergence from EU requirements may impact the development, approval, and commercialization of our products in these markets**. Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain products outside of the United States, require us to develop and implement costly compliance programs, and if violated, can lead to financial and other impacts. As we continue to expand our ~~commercialization~~ activities outside of the United States, we are subject to an increased risk of violating, and must dedicate additional resources towards avoiding inadvertently conducting activities in a manner that violates, the U. S. Foreign Corrupt Practices Act (the "FCPA"), the U. K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, and other similar foreign anti- bribery laws that prohibit corporations and individuals from corruptly paying, offering to pay, or authorizing the payment of anything of value, directly or indirectly, to any foreign government official, government staff member, political party or party official, or political candidate in an attempt to influence a person working in an official capacity or otherwise obtain an improper advantage. **We may be held responsible for conduct of the third parties with which we interact**. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the Company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Some anti- bribery laws also apply to private sector bribery. Compliance with the FCPA and other anti- bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals and other parts of the health system are operated by the government, and doctors, hospital employees, and other health care providers are considered foreign officials. Certain payments to hospital employees and other health care professionals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Many countries, including the United States, also have various lobbying laws and regulations governing the conduct of individuals and companies who interact with government officials. These laws and regulations typically include certain restrictions and disclosure obligations. If we, our employees, or third parties acting on our behalf do not comply with these laws and regulations, we may be subject to civil and criminal penalties. Many countries, including the United States, restrict the export or import of products to or from certain countries through, for example, bans, sanction programs, and boycotts. Such restrictions may preclude us from supplying products in certain countries, which could limit our growth potential. Furthermore, if we, or third parties acting on our behalf, do not comply with these restrictions, we may be subject to civil and criminal penalties. Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we continue to expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. **In addition, actions that the U. S. government and other governments have taken or threatened to take regarding tariffs and trade, and the associated uncertainty of how such actions may be implemented, may have adverse effects on the global economic environment and could also amplify these risks**. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties, suspension or debarment from government contracting, and other sanctions, and can cause reputational harm. The SEC also may bring enforcement actions against issuers for violations of the FCPA's accounting provisions. COMPETITIVE AND POLITICAL RISKS Development and commercialization of pharmaceutical products, including for PHT preparedness, are routinely subject to evolving private and public sector competition. The development and commercialization of new biopharmaceutical and medical technology products is highly competitive and subject to rapid technological advances. We will continue to face future competition from other companies and governments, universities and other non- profit research organizations in respect to our products, any products that we acquire, our current product candidates and any products we may seek to develop or commercialize in the future. The market for products can be subject to development of safer, more effective, more convenient or less costly products. The market for current products can also depend on what resources can be devoted to marketing or selling products, or how companies are positioned to adapt more quickly to new technologies, respond to scientific advances or patient preferences and needs, initiate or withstand substantial price competition and / or procure third- party licensing and collaborative arrangements. There are a number of companies with products or product candidates addressing PHT preparedness that are competing with us for both USG procurement and development resources. Factors to consider include competitors' financial, technical, marketing and selling resources as well as potential leverage that their intellectual property estates may offer. Any reduction in demand for our products or reduction or loss of development funding for our products or product candidates in favor of a competing product could lead to a loss of market share for our products and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition, operating results and cash flows. Our biologic products may face risks of competition from biosimilar manufacturers. Biological products and product candidates, which we refer to as "Biologic Products," can be affected by the approval and entry of "biosimilars" in the United States and other jurisdictions. Biosimilar products are licensed through an abbreviated pathway based on a showing that they are "highly similar" to a previously licensed product (known as the reference product) notwithstanding minor differences in clinically inactive components, and there are no clinically meaningful differences from the reference product in terms of safety, purity, and potency. Biologic Products in our current pipeline include CYFENDUS®, BioThrax® ;

and ACAM2000 ®. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business, financial condition, operating results and cash flows. NARCAN ® (naloxone HCl) Nasal Spray is currently subject to generic and branded competition and may be subject to additional generic and branded competition in the future. If demand for over-the-counter NARCAN ® Nasal Spray outpaces current estimations, there could be supply challenges to meet demand. NARCAN ® Nasal Spray was approved as an over-the-counter (“OTC”) medication **in the U. S.** on March 29, 2023 **and became available**. ~~The new OTC product was shipped out to retailers and e-commerce providers nationwide in August of 2023. Emergent is prepared to supply all segments / customers of the business with OTC product.~~ If demand for NARCAN ® Nasal Spray increases beyond our current estimates, there could be supply interruptions. **Although we have** ~~Should this occur, Emergent has~~ contingency plans to continue to provide product to those at the highest need and increase production to meet the **new anticipated increase in demand**, **such contingency plans may be unsuccessful or the implementation of such plans delayed, which could cause supply interruptions and adversely affect our business, financial condition, operating results and cash flows.** NARCAN ® Nasal Spray currently faces generic competition. In 2016, Teva Pharmaceuticals Industries Limited and Teva Pharmaceuticals USA (collectively, “Teva”) filed an Abbreviated New Drug Application (an “ANDA”) seeking regulatory approval to market a generic version of NARCAN ® Nasal Spray. In patent litigation related to Teva’s ANDA filing, a trial court decided in favor of Teva, and this decision was subsequently affirmed by the Court of Appeals for the Federal Circuit. The FDA approved Teva’s ANDA on April 19, 2019. On December 22, 2021, Teva commenced the launch of its generic naloxone nasal spray. As part of state settlements, including in Florida, Texas, Rhode Island, and West Virginia, Teva has agreed to supply Medication-Assisted Treatment (“MAT”) and generic opioid overdose reversal agents, like naloxone, to states at no cost in lieu of additional monetary compensation. The terms of these product donation agreements stretch 10 to 15 years. NARCAN ® Nasal Spray also faces generic competition from Padagis LLC (“Padagis”). Prior to Padagis’ separation from Perrigo UK FINCO Limited Partnership (“Perrigo”) in 2021, Perrigo filed its own ANDA for generic naloxone nasal spray in 2018. Emergent settled with Perrigo on February 12, 2020 providing for a license effective upon the Teva litigation decision. In June 2022, the FDA approved the ANDA and Padagis launched its prescription generic naloxone nasal spray. On July 18, 2023, the FDA approved an Rx-to-OTC switch of Padagis’ product. ~~In March April 2023 2024, the FDA approved an ANDA filed by~~ Amneal Pharmaceuticals, Inc. (“Amneal”) ~~announced that the FDA had accepted for review Amneal’s ANDA for generic naloxone nasal spray.~~ Sales of generic versions of NARCAN ® Nasal Spray at prices lower than our branded product or provided at no cost by Teva, Padagis and Amneal ~~(pending approval)~~ have the potential to erode our sales and could impact our product revenue related to NARCAN ® Nasal Spray. NARCAN ® Nasal Spray also faces branded competition from **prescription RiVive™ (naloxone HCl nasal spray 3mg), a branded product products, such as** developed by Harm Reduction Therapeutics; Kloxxado™ (naloxone HCl nasal spray 8mg), a branded product developed by Hikma Pharmaceuticals, Inc.; Amphastar Pharmaceuticals, Inc.’s naloxone injection product; Teleflex Medical Inc.’s Intranasal Mucosal Atomization Device and Zimhi™ (naloxone), a branded injectable product developed by Adamis Pharmaceuticals Corporation, **Rextovy™, (naloxone HCL nasal spray 4 mg), a branded product developed by Amphastar Pharmaceuticals, Inc. and its naloxone injection product, Teleflex Medical Inc.’s Intranasal Mucosal Atomization Device, OPVEE® (nalmefene nasal spray 2.7mg), a branded product developed by Opiant Pharmaceuticals Inc, (now a wholly owned subsidiary of Indivior PLC), and Rezenopy® (naloxone HCL nasal spray 10mg), a branded product manufactured by Summit Biosciences Inc., as well as OTC products, such as RiVive™ (naloxone HCl nasal spray 3mg), a branded product developed by Harm Reduction Therapeutics**. NARCAN ® (naloxone HCl) Nasal Spray may also face additional generic and branded competition in the future. Political or social factors may delay or impair our ability to market and sell our products and may require us to spend significant management time and financial resources to address these issues. Products developed to counter the potential impact of PHTs are subject to changing political and social environments. The political responses and social awareness of the risks of these threats on military personnel or civilians and the level of emphasis placed on such risks by the USG may vary over time. If the threat of terrorism were to decline, then the public perception of the risk on public health and safety may be reduced. This perception, as well as political or social pressures (including as a result of negative publicity we have received based on our longstanding ties to the USG), could delay or cause resistance to bringing our products in development to market or limit pricing or purchases of our products, any of which could negatively affect our revenues and our business, financial condition, operating results and cash flows. In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Lawsuits brought against us by third parties or activists, even if not successful, could require us to spend significant management time and financial resources defending the related litigation and could potentially damage the public’s perception of us and our products. Any publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of our MCMs and thereby limit the demand for our products, which would adversely affect our business, financial condition, operating results and cash flows. We may not be able to obtain orphan drug exclusivity for product candidates we may develop, and even if we do, that exclusivity may not prevent the FDA or foreign regulatory authorities from approving other competing products. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. The applicable period is seven years in the United States. In order for the FDA to grant orphan drug designation to one of our products, the agency must find, among other requirements, that the product is being or will be investigated for a condition or disease with a patient population of fewer than 200,000 individuals in the United States, or, for a vaccine, diagnostic drug, or preventive drug, it will be administered to fewer than 200,000 persons per year in the United States. Alternatively, the FDA may determine that there is no reasonable expectation that the costs of research and

development of the drug can be recovered from sales of the drug in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug designation does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same indication. In addition, even after a product receives orphan drug exclusivity, the FDA can subsequently approve the same product for the same indication if the FDA or such authorities conclude that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care; if the FDA determines that the holder of orphan drug exclusivity cannot ensure the availability of sufficient quantities of the product to meet the needs of patients with the rare disease or condition; or if the holder of orphan drug exclusivity consents to the approval of such subsequent product. Additionally, the FDA may revoke orphan drug designation if the FDA determines that the request for designation contained an untrue statement of material fact, omitted material information, or the FDA subsequently finds that the drug in fact had not been eligible for orphan drug designation at the time of submission of the request for designation. We face similar risks in the EU and other foreign jurisdictions that have comparable regulations concerning orphan drug exclusivity. INTELLECTUAL

PROPERTY RISKS Protection of our intellectual property rights is an important tool for sustaining our business and the failure to do so could impact our financial condition, operating results, and cash flows. We actively seek to protect intellectual property rights related to our Company' s assets, including patent rights, trademark rights, trade secrets, know- how and proprietary confidential information, through defense and enforcement of existing rights and pursuit of protection on new and arising innovations. Obtaining, maintaining and enforcing our intellectual property rights in the United States and other countries remains a critical component of the development and commercialization of our Company' s assets. Some of the risks associated with procurement, maintenance and enforcement of intellectual property rights include changes in patent laws or administrative patent office rules, evolving criteria and eligibility of obtaining patent protection on particular subject matter, the validity and enforceability of our intellectual property rights, the potential scope of coverage of our intellectual property rights, and / or the availability or strength of legal remedies in a particular country to defend and enforce intellectual property rights. Other risks include associated costs, such as costs of patent prosecution and maintenance and costs associated with post- grant challenges. For example, such costs include inter partes review proceedings in the United States and oppositions in Europe, as well as costs associated with litigating and enforcing patent and trademark rights. Additional risks include limitations on our extent or ability to procure, maintain or defend intellectual property rights associated with in- licensed or acquired intellectual property, where, for example, other parties (e. g., licensors) may have the first right to maintain or defend intellectual property rights in which we have an interest, or may pursue strategies that are divergent to the interest of our Company. Third- party claims of alleged patent infringement could delay, stop or affect the development and commercialization of our products and product candidates. Such challenges, while ongoing, could be costly, requiring and utilizing company resources. Such challenges, if successful, may impact marketing or launch of products, or require ongoing license and / or royalty fees associated with potential settlement agreements. These challenges may have the potential to materially harm our business, financial condition, operating results, and cash flows. We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Such license agreements or collaboration arrangements can be subject to challenges if interests or expectations under such license agreements diverge. Such challenges may be costly, risk time and resources, and could delay or impact development, commercialization or launch of our products. Potential loss of proprietary information and know- how generally carries the risk of reducing the value of our technology and products. We also rely upon unpatented proprietary technology, processes, and know- how, particularly as to our proprietary manufacturing processes. These types of proprietary confidential information, know- how, and trade secrets can be difficult to protect, and potential loss or misappropriation of this information generally carries the risk of reducing the value of our technology and products. We seek to protect this confidential information, in part, through agreements with our employees, consultants, and third parties, as well as through internal policies and audits, although these may not always be successful in protecting our proprietary confidential information, know- how, and trade secrets. Certain of our products are approved as drug products under the provisions of the FDCA, which may render ~~it~~ **them** susceptible to potential competition from generic manufacturers via the Hatch- Waxman Act and ANDA process. Other of our products may be susceptible to challenges by entry of biosimilars through the route established under the Biologics Price Competition and Innovation ~~Action~~ **Act** of 2009. Although we intend to vigorously enforce our intellectual property rights, there can be no assurance that we will prevail in our enforcement or defense of our ~~patent- intellectual property~~ rights. Our existing patents could be invalidated, found unenforceable, or ~~found not to cover a~~ **narrowed in scope. Our trademark and trade name rights and related registrations may be challenged, opposed, infringed, diluted, canceled, circumvented, declared** generic ~~form of our~~ **or product determined to be infringing on other marks**.

RISKS RELATED TO RELIANCE ON OTHER PARTIES The loss of any of our non- exclusive, sole- source or single source suppliers, a shortage of related supplies or an increase in the price of ~~inventory- materials~~ supplied to us could have an adverse effect on our business, financial condition and results of operations. We purchase certain supplies used in our manufacturing processes from non- exclusive, or single sources due to quality considerations, costs or constraints resulting from regulatory requirements. We depend on certain single- source suppliers for key materials, **manufacturing** and **other** services necessary to ~~manufacture~~ **produce and release** the majority of our products and certain product candidates. For example, we rely on a single- source supplier to provide us with Alhydrogel ® in sufficient quantities to meet our needs to manufacture CYFENDUS ® and BioThrax ® vaccines and the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for the ACAM2000 ® vaccine. We also rely on single- source suppliers for the materials necessary to produce NARCAN ® (naloxone HCl) Nasal Spray, such as the naloxone active pharmaceutical ingredient and other excipients, along with the vial, stopper and device. Where a particular single- source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products and product candidates, and the complex nature of manufacturing processes. In addition, we may lose a sole- source

supplier due to, among other things, the acquisition of a supplier by a competitor (which may cause the supplier to stop selling its products to us) or the bankruptcy of such a supplier, which may cause the supplier to cease operations. Any reduction or interruption by a sole-source supplier of the supply of materials or key components used in the manufacturing of our products or product candidates, a reduction in quality or an increase in the price of those materials or components could adversely affect us. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products and product candidates could be adversely affected and could harm our revenues, cause us to fail to satisfy contractual commitments, lead to a termination of one or more of our contracts or lead to delays in our clinical trials, any of which could be costly to us and otherwise materially harm our business, financial condition, operating results and cash flows. We depend on third parties to conduct many of our clinical and non-clinical trials. If these third parties do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates and, as a result, our business, financial condition, operating results and cash flows may suffer. We depend on third parties, such as independent clinical investigators, contract research organizations and other third-party service providers, to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with good clinical practice regulations and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization or other third party may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates. In certain cases, government entities and non-governmental organizations ("NGOs") conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. These government entities and NGOs have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. Furthermore, government entities depend on annual Congressional appropriations to fund their development efforts, which may not be approved. If we are unable to obtain any necessary third-party services on acceptable terms or if these service providers do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for our product candidates may be delayed or prevented.

LEGAL AND REPUTATIONAL RISKS

Our financial condition and operating results could be adversely impacted by unfavorable results of legal proceedings or government investigations. We are subject to various claims, legal proceedings and government investigations that have not yet been fully resolved, including stockholder derivative and putative class action lawsuits, and new matters may arise in the future. In addition, agreements entered into by us sometimes include indemnification provisions which can subject us to costs and damages in the event of a claim against an indemnified third party. The number of claims, legal proceedings and government investigations involving us, and the alleged magnitude of such claims, proceedings and government investigations, has generally increased over time and may continue to increase. Certain of these actions include, and future actual or threatened legal actions may include, claims for substantial and indeterminate amounts of damages, or may result in other actions adverse to us. For example, **in 2021**, multiple purported class action lawsuits **were have been** filed against us and certain of our current and former senior officers in the United States District Court for the District of Maryland seeking unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired shares of our common stock during various date ranges. The complaints ~~allege~~ **alleged**, among other things, that we made materially false and misleading statements regarding our procedures and quality controls relating to vaccine production, in violation of federal securities laws. **In September 2024, we and the lead plaintiffs entered into an agreement in principle to settle these claims, and on October 4, 2024, the Court granted preliminary approval of the proposed settlement, ordered notice to the settlement class and scheduled a fairness hearing to consider whether to grant final approval of the settlement. At the scheduled fairness hearing on February 27, 2025, the Court granted final approval of the settlement.** As another example, multiple stockholder derivative lawsuits were filed in The Court of Chancery of the State of Delaware and the United States District Court for the District of Maryland on behalf of the Company against certain current and former officers and directors for breach of fiduciary duties, waste of corporate assets, unjust enrichment and insider trading, each allegation related to the Company's capabilities to manufacture COVID-19 vaccine bulk drug substance. In addition to monetary damages, the complaints seek the implementation of multiple corporate governance and internal policy changes. Regardless of merit, litigation can be both time-consuming and disruptive to our operations and cause significant expense and diversion of management's attention. The outcome of litigation or government investigations is also inherently uncertain. If one or more legal matters were resolved against us or an indemnified third party in a reporting period for amounts above management's expectations, our financial condition and operating results for that reporting period could be materially adversely affected. Further, such an outcome could result in significant compensatory, punitive or trebled monetary damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief against us and could require us to change our business practices or limit our ability to offer certain products and services, all of which could materially adversely affect our financial condition and operating results. While we maintain insurance coverage for certain types of claims, such insurance coverage may be insufficient to cover all losses or all types of claims that may arise. We rely significantly on information technology systems and any cyber-security incidents, unauthorized access or other failure, inadequacy, interruption or security lapse of that technology could harm our ability to operate our business effectively or result in data leakage of proprietary or confidential business or employee information. 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. We previously contracted with the USG and pharmaceutical

companies for the development and manufacture of a significant quantity of COVID- 19 vaccines, which raised our security profile and heightened potential risks that malicious actors may seek to disrupt our systems or misappropriate our information. The size and complexity of our computer systems and those of many of our business partners, collaborators and other third parties make them potentially vulnerable to interruption, invasion, computer viruses, destruction, unauthorized or malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes. Our systems and information are also potentially vulnerable to ~~cyber security~~ **cybersecurity** incidents through user error, phishing scams, or malfeasance, as well as ~~cyber security~~ incidents involving our employees, business partners, collaborators or other third parties, any of which may expose sensitive data to unauthorized persons. Our systems and those of our business partners and collaborators have in the past been, and in the future likely will be subject to computer viruses, malicious codes, unauthorized access and other ~~cyber security~~ **cybersecurity** incidents. We are not aware of any significant impact on our operations or financial results from such incidents ~~although, as of the date of this report, we are assessing the potential impact of a cyber security incident involving misuse of authorized access by a business partner of which we became aware in October 2023~~. No system of protection is adequate to protect against all such threats, even if they are deemed to be industry standard, and there can be no assurance that we will be able to repel any such attacks. ~~Cyber security~~ **Cybersecurity** incidents could lead to the loss of trade secrets or other intellectual property or the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others. Responding to any such threats may also be expensive and time- consuming. Any such unauthorized access to our information, whether through an incident involving our information technology systems or those of our business partners, collaborators or other third parties, could disrupt our business operations, result in the loss of assets, and have a material adverse effect on our reputation, business, financial condition, or results of operations. While the Company has experienced non- material cyber incidents involving third- party vendors, the Company' s continued use of third parties in its business yields the potential for material ~~cyber security~~ **cybersecurity** incidents that may harm business operations. A significant business disruption or a breach in security resulting in misappropriation, theft or sabotage with respect to proprietary or confidential business or employee information could result in significant financial losses, legal, business or reputational harm to us, compromise our business prospects and our commitments to the USG or other customers, any of which could materially and adversely affect our business, financial condition and operating results. We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition and results of operations. We face an inherent risk of product liability exposure related to the sale of our products, any other products that we successfully acquire or develop and the testing of our product candidates in clinical trials. One measure of protection against such lawsuits is coverage under the PREP Act, which was signed into law in December 2005. The PREP Act creates liability protection for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide liability protection from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure under a government contract. The Secretary of HHS has issued PREP Act declarations covering countermeasures for smallpox, mpox, and other orthopox; anthrax; and botulinum toxin. These declarations apply to certain of our products, namely BioThrax ®, ACAM2000 ®, **CYFENDUS ®**, raxibacumab, Anthrasil ®, BAT ® and VIGIV **CNJ-016 ®** products, as covered countermeasures. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct or for cases brought in non- U. S. tribunals or under non- U. S. law. We cannot predict whether the Secretary of HHS will renew the declarations when they expire, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our products or product candidates. Additionally, certain of our products, namely BioThrax ® and ~~RSDL ®~~, are under the SAFETY Act, which provides certain product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Although BioThrax ® ~~is~~ and ~~RSDL ®~~ are designated and certified under the SAFETY Act, the law may not provide adequate protection from claims made against us. If we cannot successfully defend ourselves against future claims that our products or product candidates caused injuries and if we are not entitled to indemnity by the USG, or the USG does not honor its obligations to us under the PREP Act or SAFETY Act, or if the liability protections under the PREP Act and SAFETY Act are not adequate to cover all claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in: • decreased demand or withdrawal of a product; • injury to our reputation; • withdrawal of clinical trial participants; • costs to defend the related litigation; • substantial monetary awards to trial participants or patients; • loss of revenue; and • an inability to commercialize products that we may develop. The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. For example, we may not have sufficient insurance against potential liabilities associated with a possible large- scale deployment of BioThrax ® vaccine as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax ®, raxibacumab, ACAM2000 ®, **CYFENDUS ®**, Anthrasil ®, BAT ® and VIGIV **CNJ-016 ®** products, and SAFETY Act protection for BioThrax ® ~~and RSDL ®~~ products in addition to our insurance coverage to help mitigate our product liability exposure for these products. Additionally, potential product liability claims related to our commercial products, including NARCAN ® (naloxone HCl) Nasal Spray, may be made by patients, health care providers or others who sell or consume these products. Such claims may be made even with respect to those products that possess regulatory approval for commercial sale. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition, operating results and cash flows. **FINANCIAL RISKS** **Our level of** ~~We have incurred significant indebtedness in connection with our acquisitions and the terms servicing our debt requires a significant amount of cash~~ **our indebtedness could adversely affect our business and liquidity position**. We may not have sufficient cash flow from our operations to pay our substantial debt. **As described in Note 10, " Debt " in the Notes to Consolidated Financial**

Statements in Part II, Item 8. of this Annual Report on Form 10- K, as of December 31, 2024, we have approximately \$ 700. 0 million of total indebtedness, which includes our outstanding Senior Unsecured Notes. Our level of indebtedness could have important consequences for us, including: • limiting our ability to obtain additional financing, if needed, for working capital, capital expenditures, acquisitions, debt service requirements or other purposes; • increasing our vulnerability to adverse economic, industry or competitive developments; • limiting our flexibility in planning for, or reacting to, changes in our business and industry; and • placing us at a competitive disadvantage compared to our competitors with less debt. Our indebtedness may increase from time to time for various reasons, including fluctuations in operating results, working capital needs, capital expenditures, acquisitions and / or joint ventures. The cost and level of our debt could negatively impact our liquidity, future financing costs and financial results, while potential credit rating downgrades or adverse market conditions could increase borrowing costs or limit access to capital. Our cash flow and capital resources may not be sufficient to meet our debt obligations, and alternative financing measures may not be available on terms that are acceptable to us, or at all. Our ability to service make scheduled payments of the principal of, to pay interest on or to further-refinance, our indebtedness debt depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing can have significant adverse consequences for our business, including: • requiring us to dedicate a substantial portion of cash flows from operations to payment on our debt, which would reduce available funds for other corporate initiatives; • increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase, to the extent we are unable to offset such risk through our hedging instruments; • subjecting us, as under our Senior Secured Credit Facilities and the indenture governing the Senior Unsecured Notes, to restrictive covenants that reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing; • requiring us to pledge our assets as collateral, which could reduce limit our ability to obtain additional debt financing financial flexibility ; and • increasing limiting our flexibility in planning for, or our reacting exposure to , general adverse economic and industry conditions , furthering disadvantaging ; and • placing us against at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity. We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under our indebtedness. In addition, failure to comply with the covenants under our Senior Secured Credit Facilities and other debt agreements, including the maintenance of a specified gross consolidated net leverage ratio, debt service fixed charge coverage ratio and consolidated EBITDA level, minimum liquidity level and required liquidity raise under our Senior Secured Credit Facilities , and the additional terms and conditions imposed by the Forbearance Agreement and Sixth Amendment to Amended and Restated Credit Agreement, dated February 29, 2024 (the " Forbearance Agreement and Amendment") could result in an event of default under those agreements. An event of default could result in the acceleration of amounts due under a particular debt agreement and a cross default and acceleration under other debt agreements . If such events occur , and we may not have sufficient funds to pay or be able to obtain additional financing options to meet these obligations make any accelerated payments. Our current indebtedness restricts and any additional debt financing may restrict the operation of our business and limit the cash available for investment in our business operations. The Senior Secured Credit Facilities include the Term Loan Facility, which had an outstanding principal balance of \$ 198. 250. 2-0 million as of December 31, 2023-2024 , and the ability to borrow up to \$ 300. 100. 0 million under our the Revolving Credit Facility under which Agreement (subject to certain adjustments described therein). In addition, we have had \$ 219. 2 million of outstanding borrowings as of December 31, 2023. On August 7, 2020, we completed an offering of \$ 450. 0 million aggregate principal amount of \$ 450. 0 million of our Senior Unsecured Notes. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing can have significant adverse consequences for our business, including: • the level, timing and cost of product sales and bioservices Bioservices ; • the extent to which we acquire or invest in and integrate companies, businesses, products or technologies; • the acquisition of new facilities and capital improvements to new or existing facilities; • the payment obligations under our indebtedness; • the scope, progress, results and costs of our development activities; • our ability to obtain funding from collaborative partners, government entities and non- governmental organizations for our development programs; • the extent to which we repurchase common stock under any future share repurchase program; and • the costs of commercialization activities, including product marketing, sales and distribution. In addition, our Senior Secured Credit Facilities and our Senior Unsecured Notes each contain cross- default provisions whereby a default under one agreement would likely result in cross defaults under agreements covering other indebtedness. For example, if we default under the Senior Secured Credit Facilities, the lenders would have the right to accelerate the repayment of borrowings under the Senior Secured Credit Facilities, which would result in a cross- default and acceleration of the Company' s obligations under the Senior Unsecured Notes. The occurrence of a default under any of these arrangements would permit the holders of the notes or the lenders under our Senior Secured Credit Facilities to declare all amounts outstanding under those borrowing arrangements to be immediately due and payable, and there is no assurance that we would have sufficient funds to satisfy any such accelerated obligations. Our hedging programs have been, and any hedging program we initiate in the future will be, subject to counterparty default risk. From time to time, we manage our interest rate risk in part by entering into interest rate swaps with a number of counterparties to swap a portion of our indebtedness that is based on variable interest rates to a fixed rate. As a result, when we are party to such interest rate swaps, we are subject to the risk that the counterparty to one or more of these contracts defaults on its performance under the contract. During an economic downturn, the counterparty' s financial condition may deteriorate rapidly and with little notice and we may be unable to take action to protect our exposure. In the event of a counterparty default, we could incur losses, which may harm our business and financial condition. In the event that one or more of our counterparties becomes insolvent or files for bankruptcy, our ability to eventually recover any losses suffered as a result of that counterparty' s default may be limited by the liquidity of the counterparty. We may require significant additional

funding to be able **unable to continue to progress on or implement our strategic plans and sustain our current operating performance, in which case our business, results of operations, financial condition and prospects could be adversely affected, and which may give rise to substantial doubt regarding our ability** to continue as a going concern and we may be unable to raise capital when needed or on acceptable terms, which would harm our ability to grow our business, and our results of operations and financial condition. In addition, any capital we raise may result in dilution to our current stockholders. As of December 31, 2023-2024, we had unrestricted cash and cash equivalents of \$ 111-99.75 million and remaining capacity under our **the Revolving Credit Facility Agreement** of \$ 80-100.30 million. Also as of December 31, 2023-2024, there was **we had borrowings of** \$ 219-250.02 million outstanding on our Revolving Credit Facility and \$ 198.2 million on our Term Loan Facility that mature in May 2025. We are not in compliance with certain provisions of the Senior Credit Facilities, most notably that we comply with the minimum consolidated EBITDA covenant and that our financial statements not contain a "going concern" qualification. In addition, it is unlikely that we will be able to comply with the requirement in the Credit Agreement Amendment (as define below) that we raise not less than \$ 75-450.0 million through the issuance of equity and/or unsecured indebtedness by April 30, 2024. As a result, the Company determined that there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements included in this Annual Report on Form 10-K were issued. On February 29, 2024, the requisite lenders under the Senior **Unsecured Notes** Credit Facilities agreed to enter into the Forbearance Agreement and Amendment to, among other things, (a) provide that the Administrative Agent and the Lenders forbear from exercising all rights and remedies under the Existing Credit Agreement and the other related loan documents arising from the occurrence and continuation of certain specified events of default during a forbearance period (the "Forbearance Period") between the forbearance effective date until the earlier to occur of (x) 5:00 p. m. on April 30, 2024 and (y) the occurrence of any event of default (other than the specified events of default) or default under the Forbearance Agreement and Amendment and notice by the Administrative Agent to the Company of the termination of the Forbearance Period and (b) provide consent by the required revolving credit lenders to make further loans to the Company or other extensions of credit to the credit parties during the Forbearance Period, notwithstanding **outstanding** the occurrence of the specified events of default, subject to certain conditions set forth in the Forbearance Agreement and Amendment, including a limit on Revolving Credit Facility indebtedness of \$ 270 million. The Company **may** does not expect to be in compliance **unable to comply** with debt covenants in future periods without additional sources of liquidity or future amendments to or forbearance arrangements under the Credit Agreement. We will need to obtain substantial additional funding in connection with our continuing operations, which cannot be assured. If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. **In Our Registration Statement on Form S-3 that related to our ATM Program expired on August 9, 2021-2024, we. We cannot sell any shares under the ATM Program until a new Registration Statement on Form S-3 is filed and a shelf registration statement, which immediately became becomes effective under SEC rules.** As a result of the delayed filing of certain of our periodic reports with the SEC, we are not currently eligible to register the offer and sale of our securities using the shelf registration statement and we will not become eligible until we have timely filed certain periodic reports required under the Securities Exchange Act of 1934 for 12 consecutive calendar months. There can be no assurance that we will be eligible to file a shelf registration statement or to have such a shelf registration statement become effective **after such period in the future**, which may inhibit our ability to access the capital markets to raise funds. If we raise funds by issuing equity securities, including through our ATM Program **a new shelf registrations statement**, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants, like those contained in our Senior Secured Credit Facilities and the indenture governing the Senior Unsecured Notes, limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us. Our Senior Secured Credit Facilities as well as the indenture governing the Senior Unsecured Notes restrict our ability to incur additional indebtedness. Economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, operating results, financial condition and cash flows would be adversely affected, and we could be forced to delay, reduce the scope of or eliminate many of our planned activities. We may not maintain profitability in future periods or on a consistent basis. Our profitability has been substantially dependent on product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the USG. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis. Impairment charges to our intangible assets or property, plant and equipment could have a material adverse effect on our business, results of operations and financial condition. In accordance with GAAP, we are required to assess the value of our intangible assets and goodwill annually, or more frequently whenever events or changes in circumstances indicate potential impairment, such as changing market conditions or any changes in key assumptions. If the testing performed indicates that an asset may not be recoverable, we are required to record a non-cash impairment charge for the difference between the carrying value of the asset and its implied fair value in the period the determination is made. We also periodically monitor the remaining net book values of our property, plant and equipment, or whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. For example, we performed recoverability tests on **certain the Bayview and Rockville** asset groups within the Bioservices reporting unit during the three months ended June 30, 2023-2024, and **allocated** and recognized a non-cash impairment charge of \$ 306-27.72 million during the three months ended June 30, 2023-2024 related to certain Bioservices long-lived assets. **In addition, we annually perform a goodwill impairment evaluation, during the fourth quarter, or sooner if triggering events are identified. During the three months ended September 30, 2023 as a result of continued market volatility, including significant declines in**

our market capitalization and revised financial outlook, we determined that a triggering event had occurred that required an evaluation of our goodwill for potential impairment. As a result of the quantitative assessments, we determined that our goodwill, which related to the MCM reporting unit within the Products segment, was fully impaired and recorded a \$ 218.2 million non-cash goodwill impairment charge during the three months ended September 30, 2023. We have a significant amount of intangible assets and property, plant and equipment on our balance sheet. The impairment tests require us to make an estimate of the fair value of our reporting units. An impairment could be recorded as a result of changes in assumptions, estimates or circumstances, some of which are beyond our control. Since a number of factors may influence determinations of fair value, we are unable to predict whether impairments of intangible assets and property, plant and equipment will occur in the future, and we can provide no assurance that continued conditions will not result in future impairments of these assets. The future occurrence of a potential indicator of impairment could include matters such as (i) a decrease in expected net earnings, (ii) adverse equity market conditions, (iii) a decline in current market multiples, (iv) a decline in our common stock price, (v) a significant adverse change in legal factors or the general business climate, and (vi) an adverse action or assessment by a regulator. Any such impairment would result in us recognizing a non-cash charge in our Consolidated Balance Sheets, which could adversely affect our business, results of operations and financial condition. The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. **Any** We have identified material weaknesses **weakness** in our internal control over financial reporting **and could** have restated prior period **an adverse effect on our business and financial results and our ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our common stock. Internal control over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of** financial statements that resulted from one of these material weaknesses, which may raise questions regarding the accuracy and reliability of **may not prevent our or financial detect** statements **misstatements** and our ability to report accurately in the future. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. **Failure** During the process of preparing the financial statements as of and for the year ended December 31, 2022, we determined that we had a material weakness related to **maintain effective** our inventory accounting. Subsequently, in connection with the preparation of the financial statements as of and for the periods ended September 30, 2023, we determined that we had a material weakness related to the calculation and review of the Company's net state deferred tax liability and that this material weakness had existed as of December 31, 2022 and resulted in a material misstatement to our consolidated financial statements for the period ended December 31, 2022. Due to the existence of these material weaknesses, our management concluded that as of December 31, 2022 our internal control over financial reporting was not effective, **or lapses in disclosure controls and procedures, could impact our** we were required to restate the financial statements included in **information and disclosures, require significant resources to remediate, and expose us to legal our or regulatory proceedings** Original Form 10-K and filing Amendment No. 1 to the Original Form 10-K for the fiscal year ended December 31, 2022. We determined that we remediated **regularly review and update** our internal **controls** weakness with respect to inventory accounting as of March 31, 2023 and **disclosure controls and procedures. In addition,** we are **required under** taking steps to remediate the material weakness related to the calculation and review of the Company's net state deferred tax liability. In addition, we have restated our financial statements for the fiscal year ended December 31, 2022 to correct the errors that were identified as a result of the material weakness regarding our calculation and review of the Company's net state deferred tax liability, and corrected other **the Sarbanes** unrelated errors that were either unrecorded or addressed as out- **Oxley Act** of 2002 **period adjustments in previously filed financial statements that were not material, individually or in the aggregate, to report annually on** those financial statements. However, we cannot provide any assurance that the measures we have taken to date and we intend to implement will be sufficient to remediate the material weakness regarding state deferred taxes that we have identified, or to avoid additional material weaknesses from occurring in the future. The material weaknesses in our internal control over financial reporting and the restatement of our prior financial statements may raise significant questions regarding the accuracy and reliability of our filed financial statements and our ability to report in an accurate and timely manner in the future. These material weaknesses and resulting errors in our financial statements, or those that may occur in the future, could have an adverse effect on our ability to meet our reporting obligations, which could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, harm our reputation, business and financial results, and expose us to stockholder litigation and sanctions or investigations by the SEC or other regulatory authorities. The expansion of our international operations increases our risk of exposure to credit losses. As we continue to expand our business activities with foreign governments in certain countries that have experienced deterioration in credit and economic conditions or otherwise, our exposure to uncollectible accounts will rise. Global economic conditions and liquidity issues in certain countries have resulted and may continue to result in delays in the collection of accounts receivable and may result in credit losses. Future governmental actions and customer specific actions may require us to re-evaluate the collectability of our accounts receivable and we may potentially incur credit losses that materially impact our operating results.

RISKS RELATED TO STRATEGIC ACQUISITIONS, DIVESTITURES AND COLLABORATIONS We may not be successful in identifying, effectively evaluating, structuring, acquiring or in-licensing, and developing and commercializing additional products on favorable terms, or at all. Competition for attractive product opportunities is intense and may require us to devote substantial resources, both managerial and financial, to an acquisition opportunity. A number of more established companies are also pursuing strategies to acquire or in-license products in the biopharmaceutical field. These companies may have a competitive advantage over us due to their size, cash resources, cost of capital, effective tax rate and greater clinical development and commercialization capabilities. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote significant resources to

potential acquisitions that are never completed. Even if we are successful in acquiring a company or product, it may not result in a successfully developed or commercialized product or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. Moreover, the cost of acquiring other companies or in-licensing products could be substantial, and in order to acquire companies or new products, we may need to incur substantial debt or issue dilutive securities. If we are unsuccessful in our efforts to identify and acquire other companies, products, or in-license and develop additional products, or if we acquire or in-license unproductive assets, it could have a material adverse effect on the growth of our business, and we could be compelled to record significant impairment charges to write-down the carrying value of our acquired intangible assets, which could materially harm our business, financial condition, operating results and cash flows. Our failure to successfully integrate acquired businesses and / or assets into our operations could adversely affect our ability to realize the benefits of such acquisitions and, therefore, to grow our business. We may not be able to integrate any acquired business successfully or operate any acquired business profitably. In addition, cost synergies, if achieved at all, may be less than we expect, or may take greater time to achieve than we anticipate. Issues that could delay or prevent successful integration or cost synergies of an acquired business or products include, among others: • retaining existing customers and attracting new customers; • retaining key employees; • diversion of management attention and resources; • conforming internal controls, policies and procedures, business cultures and compensation programs; • consolidating corporate and administrative infrastructures; • successfully executing technology transfers and obtaining required regulatory approvals; • consolidating sales and marketing operations; • identifying and eliminating redundant and underperforming operations and assets; • assumption of known and unknown liabilities; • coordinating geographically dispersed organizations; • managing tax costs or inefficiencies associated with integrating operations; and • risks associated with intellectual property rights related to an acquisition or collaboration, including but not limited to, license rights, freedom-to-operate, litigation, and loss of proprietary confidential information, know-how, and trade secrets. If we are unable to successfully integrate pending and future acquisitions with our existing businesses, or operate any acquired business profitably, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect the growth of our business, financial condition, operating results and cash flows. We may not realize the expected benefits of the sale of our travel health business to Bavarian Nordic, **the sale of RSDL® to SERB, and the sale of our drug product facility in Baltimore- Camden to Bora**. On May 15, 2023, pursuant to the Purchase and Sale Agreement, we completed the previously announced sale to Bavarian Nordic of our travel health business, including rights to Vaxchora® and Vivotif®, as well as our development-stage chikungunya vaccine candidate CHIKV VLP, our manufacturing site in Bern, Switzerland and certain of our development facilities in San Diego, California for a cash purchase price of \$ 270. 2 million, subject to certain customary adjustments. In addition, we may receive milestone payments of up to \$ 80. 0 million related to the development of CHIKV VLP and receipt of marketing approval and authorization in the U. S. and Europe, and sales-based milestone payments of up to \$ 30. 0 million based on aggregate net sales of Vaxchora® and Vivotif® in calendar year 2026. **On June 20, 2024, Cangene bioPharma LLC (“ Cangene ”), a subsidiary of the Company (together with Cangene, the “ Seller ”), entered into an Asset Purchase Agreement with Bora, under which the Seller sold its drug product facility in Baltimore- Camden for a cash purchase price of approximately \$ 35. 0 million. The transaction closed on August 20, 2024. On July 31, 2024, we entered into the Stock and Asset Purchase Agreement with SERB Pharmaceuticals, through its wholly owned subsidiary BTG International Inc. (collectively, “ SERB ”), pursuant to which, among other things, we sold our worldwide rights to RSDL®, to SERB (the “ RSDL® Transaction ”) for a cash purchase price of \$ 75. 0 million, exclusive of customary closing adjustments related to inventory. In addition, SERB will pay us a \$ 5. 0 million payment upon achievement of a milestone relating to sourcing of a certain component of RSDL® decontamination lotion. The Transaction also included the sale to SERB of all the outstanding capital stock of Emergent Protective Products USA Inc. (“ EPPU ”), a wholly owned subsidiary of the Company, which leases a manufacturing facility in Hattiesburg, Mississippi, as well as certain assets related to RSDL®, including intellectual property rights, contract rights, inventory and marketing authorizations. In addition, the employees of EPPU joined SERB in connection with the RSDL® Transaction**. There can be no assurance that we will be able to realize in full the expected benefits of ~~the these transaction-transactions~~, **including as to whether any milestone payments will be received**. If we are unable to or do not realize the expected strategic, economic, or other benefits of ~~the these transaction-transactions~~, it could adversely affect our business and financial position.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK In recent years, some stockholders have placed increasing pressure on publicly traded companies in our industry and others to effect changes to corporate governance practices, executive compensation practices, social and environmental practices and to undertake certain corporate actions. This may be true even if they only hold a minority of shares. In addition, ~~many certain~~ institutional investors ~~are increasingly may continue to focused~~ **focus** on **sustainability** environmental, social, and corporate **responsibility** governance (“ ESG”) factors. These investors may be seeking enhanced ESG disclosures or to implement policies adverse to our business. There can be no assurances that stockholders will not publicly advocate for us to make corporate governance changes or engage in certain corporate actions. Responding to challenges from stockholders, such as proxy contests, media campaigns or other public or private means, could be costly and time consuming and could have an adverse effect on our reputation and divert the attention and resources of management and our board of directors, which could have an adverse effect on our business and operational results. Any such stockholder actions or requests, or the mere public presence of stockholders with a reputation for taking such actions among our investor base, could also cause the market price of our common stock to experience periods of significant volatility. Provisions in our certificate of incorporation and by-laws and under Delaware law may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable. Provisions in our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other changes in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts

by our stockholders to replace or remove our management. These provisions include: • the classification of our directors; • limitations on changing the size of our board of directors; • limitations on the removal of directors; • limitations on filling vacancies on the board of directors; • advance notice requirements for stockholder nominations of candidates for election to the board of directors and other proposals to be voted on at meetings of stockholders; • the inability of stockholders to act by written consent; • the inability of stockholders to call special meetings; and • the ability of our board of directors to designate the terms of and issue a new series of preferred stock without stockholder approval. The affirmative vote of a majority of our board of directors or the holders of our capital stock representing at least 75 % of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation or by- laws. The affirmative vote of either a majority of the directors present at a meeting of our board of directors or holders of our capital stock representing at least 75 % of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by- laws. In addition, we are subject to Section 203 of the Delaware General Corporation Law (" Section 203"). In general and subject to certain exceptions, Section 203 prohibits a publicly- held corporation from engaging in a business combination with an interested stockholder, generally a person which, together with its affiliates, owns or within the last three years has owned 15 % or more of the corporation' s voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us. Our board of directors may adopt a new stockholder rights plan without stockholder approval, which could prevent a change in control of us in instances in which some stockholders may believe a change in control is in their best interests. Our board of directors may adopt a stockholder rights plan without stockholder approval, which may have anti- takeover effects, potentially preventing a change in control of us in instances in which some stockholders may believe a change in control is in their best interests. This could cause substantial dilution to a person or group that attempts to acquire us on terms that our board of directors does not believe are in our best interests or those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. Our stock price is volatile, and purchasers of our common stock could incur substantial losses. Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this “ Risk Factors ” section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. **From November 15, 2006, for the five- year period beginning January 1, 2006, 2020 and ending December 31, 2023, our common stock first began trading on the New York Stock Exchange, through December 31, 2023, our common stock has traded as high as \$ 137.134 . 61-94 per share and as low as \$ 1. 81-50 per share.** The market price of our common stock may be influenced by many factors, including, among others: • contracts, decisions and procurement policies by the USG affecting our anthrax vaccines and our other products and product candidates; • the success of competitive products or technologies; • results of clinical and non- clinical trials of our product candidates; • announcements of acquisitions, financings or other transactions by us; • litigation or legal proceedings; • public concern as to the safety of our products; • termination or delay of a development program; • the recruitment or departure of key personnel; • variations in our product revenue and profitability; and • the other factors described in this “ Risk Factors ” section. Because we currently do not pay dividends, investors will benefit from an investment in our common stock only if it appreciates in value. We currently do not pay dividends on our common stock. Our Senior Secured Credit Facilities and the indenture governing our Senior Unsecured Notes limit and any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders based on current expectations. Future sales of our common stock or other securities convertible into common stock, or the perception that such sales or issuances could occur, could result in dilution of our stockholders and could cause our share price to decline. Our board of directors is authorized, without stockholder approval, to cause us to issue additional shares of our common stock or to raise capital through the issuance of preferred shares or the sale of debt securities that are convertible into common stock, options, warrants and other rights, on terms and for consideration as our board of directors in its sole discretion may determine. **In addition, under the Credit Agreement Amendment, we are required to increase our liquidity by April 30, 2024 by raising at least \$ 75 million of equity or unsecured indebtedness. We also may require substantial or desire additional funding in the future to be able to continue as a going concern** and we may seek to achieve such funding through future sales of our common stock or other securities convertible into our common stock. Sales of substantial amounts of our common stock or the issuance of preferred shares, convertible debt, options, restricted stock units, performance stock units, warrants and other rights, or the perception that such sales or issuances could occur could cause the market price of our common stock to decrease significantly. As of December 31, ~~2023~~ **2024**, we had ~~54,329,52~~ **542,167,256** shares of common stock issued and outstanding. We cannot predict the effect, if any, of future sales of our common stock or any preferred shares, convertible debt securities, options, restricted stock units, performance stock units, warrants or other rights or the availability of our common stock for future sales on the value of our common stock.

GENERAL RISK FACTORS Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business. Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel (including quality and manufacturing personnel). If we are unable to retain the services of one or more of the principal members of senior management or other key employees, our ability to implement our business strategy could be materially harmed. From time to time, there may be changes in our senior management team resulting from the hiring or departure of executives. For example, we hired a new Chief Executive Officer in February 2024. Our new Chief Executive Officer **is** will be critical to executing on and achieving our vision, strategic direction,

and business objectives .~~If we are unable to successfully transition leadership to our new Chief Executive Officer, our business, results of operations and financial conditions could be adversely affected.~~ In addition, we face intense competition for qualified employees from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time- consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package to attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business. 55