Risk Factors Comparison 2025-03-03 to 2024-02-29 Form: 10-K

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

You should carefully consider the following risk factors and the other information contained elsewhere in this Annual Report **on Form 10- K** before making an investment in our securities. If any of the following risks occur, our business, financial condition or operating results could be materially harmed. An investment in our securities is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. The risks described below are not the only ones that our business faces. Additional risks not currently known to us or that we currently deem to be immaterial may adversely impact our business in the future **. Investors should also refer to the other information contained or incorporated by reference in this Annual Report on Form 10- K, including our financial statements and related notes, and our other filings from time to time with the SEC** . Risks Related to Commercialization If we obtain U. S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approval for a product candidate and do not achieve broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from product sales will be limited. We currently have one marketed product, BRIUMVI, which received approval from the FDA on December 28, 2022, for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing- remitting disease, and active secondary progressive disease, in adults. Additionally, BRIUMVI received approval from the European Commission (EC) on June 1, 2023, and later in 2023, from the Medicines and Healthcare products Regulatory Agency (MHRA) for the treatment of adult patients with RMS who have active disease defined by clinical or imaging features in the EU and UK, respectively. **We** ~~While we have initiated the commercial launch of BRIUMVI in the U. S., we~~ have limited experience as a commercial company, and our ability to successfully overcome the risks associated with commercializing drugs in the biopharmaceutical industry, including the risk that our products do not achieve an adequate level of acceptance, remains uncertain. BRIUMVI, as well as other drugs that we may bring to the market in the future, may not gain market acceptance by physicians, patients, third- party payors and others in the healthcare community. As a result, we may not generate significant revenues or meet our revenue **and operating expenses** projections or guidance and may not become profitable. The degree of market acceptance of BRIUMVI, as well as any future product candidates for which we may receive marketing approval, will depend on a number of factors, including: ● the timing of our receipt of marketing approvals, the terms of such approvals, and the countries in which such approvals are obtained; ● the efficacy, safety and tolerability as demonstrated in clinical trials and as compared to alternative treatments; ● the timing of market introduction of BRIUMVI and any of our product candidates, as well as competitive products; ● the indications for which our products are approved, and other aspects of the approved labeling for such products; ● acceptance by physicians, advanced practitioners, major operators of neurology clinics, and patients of our products as safe, tolerable and effective treatments; ● the potential and perceived advantages or disadvantages of our products compared to alternative treatments; ● our ability to offer our products for sale at competitive prices; ● the availability of adequate reimbursement by third- party payors and government authorities; ● the extent of patient cost- sharing obligations, including copays and deductibles; ● changes in regulatory requirements by government authorities for our products; ● relative convenience and ease of administration; ● the prevalence and severity of side effects and adverse events; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the effectiveness of our sales and marketing efforts, as well as those of any current or future partners; ● protecting our rights in our intellectual property portfolio; ● our ability to maintain a reliable supply of our products that meets market demand; and ● favorable or unfavorable publicity relating to our products or relating to the Company. In addition, global health concerns ~~such as the COVID- 19 pandemic~~ could impact commercialization of BRIUMVI. Patients and healthcare providers have raised concerns that immunosuppressive products like anti- CD20 antibodies and other B- cell targeted agents may increase the risk of acquiring viruses ~~such as COVID- 19~~ or lead to more severe complications or outcomes upon infection, including death. These or other similar concerns may impact the commercial potential for BRIUMVI and other immunosuppressive products that we have in development. If BRIUMVI, or any future product candidates for which we receive regulatory approval, do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and we may not become or remain profitable, which would have a material adverse effect on our business. We may be subject to limitations on the indicated uses or requirements to fulfill certain post- marketing requirements to the satisfaction of regulatory authorities or may be unable to maintain marketing approval for BRIUMVI or future products that we may bring to market. Regulatory approvals for our product or any of our product candidates may be subject to conditions and limitations on the approved indicated uses for which the product may be marketed or contain requirements **or commitments** for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance **and pharmacovigilance** to monitor the safety and efficacy of the approved product candidate. For example, with respect to the FDA' s approval of BRIUMVI for RMS, the approval is subject to certain post- marketing requirements and commitments, including long- term safety studies, as well as studies to evaluate the effects of BRIUMVI in pregnant women and pediatric populations, among others. Similar post- approval studies are required by other regulatory authorities outside of the U. S., including but not limited to, the EMA in the EU and the MHRA in the ~~United Kingdom (~~ UK ~~)~~. These studies are highly specialized in their design and conduct and are associated with considerable expenses, and based on the outcome, could result in further labeling restrictions that could impair or restrict the way in which we are able to market BRIUMVI, or negatively impact its overall clinical profile **. On September 18, 2024, we announced updated and long- term data from the Open- Label Extension of our ULTIMATE I & II Phase 3**

studies demonstrating a consistent safety profile, but the ultimate outcome of these and other studies remains uncertain . In addition, with respect to BRIUMVI and any product candidate that the FDA or a comparable foreign regulatory authority approves, the manufacturing processes, testing, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices (cGMPs), with Good Clinical Practices (GCPs), for any clinical trials that we conduct post- approval, and with Good Laboratory Practices (GLPs) ~~,~~ for any nonclinical studies. Later discovery of previously unknown problems with a product or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things, restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, mandatory safety labeling changes or product recalls, suspension or revocation of product approvals, product seizure or detention, refusal to permit the import or export of products, and injunctions or the imposition of civil or criminal penalties, all of which would adversely affect our business, prospects and ability to achieve or sustain profitability. BRIUMVI, and any of our product candidates for which we in the future obtain approval, may, after approval, be found to cause undesirable side effects that could result in significant negative consequences following commercialization. As BRIUMVI or any future approved products are used more widely or for a longer duration after being brought to market, data may emerge from clinical studies, including confirmatory or other post- marketing studies, or from adverse event reporting **or pharmacovigilance** , that may affect the commercial potential of our products. For example, as additional patients are exposed for longer durations to a product in the commercial and clinical settings, it is unknown whether greater frequency and / or severity of adverse events are likely to occur or whether an acceptable safety and tolerability profile will continue to be demonstrated. If we or others identify unexpected side effects caused by BRIUMVI or other products or product candidates within the RMS space following introduction into the market, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw approval or limit the approved indications for use of such products; ● regulatory authorities may require the addition of new or different labeling statements, including warnings or boxed warnings, precautions, or contraindications that could diminish the usage of the product or otherwise limit the commercial success of the affected product; ● we may be required to change the way such drug candidates are distributed or administered, or to conduct additional clinical trials; ● regulatory authorities may require a Risk Evaluation and Mitigation Strategy (REMS), a plan to mitigate risks, which could include a Medication Guide, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools; ● we may be subject to regulatory investigations and government enforcement actions; ● we may decide to remove such drug candidates from the marketplace; ● we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model; ● we could be sued and held liable for injury caused to individuals exposed to or taking our products; and ● our reputation may suffer. Any one or a combination of these events could prevent us from maintaining regulatory approval and achieving or maintaining market acceptance of the affected product **and / or other products** or could substantially increase the costs and expenses of commercializing the affected product **and / or other products** , which in turn could significantly impact our ability to successfully commercialize our drug candidates and generate revenues. The incidence and prevalence for target patient populations of BRIUMVI and our product candidates, including ~~TG- 1701 and TG- 1801 in B- cell disorders and~~ azer- cel in non- oncology indications, have not been established with precision. If the market opportunities for BRIUMVI and our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected. The precise incidence and / or prevalence of RMS are unknown. Our projections for BRIUMVI in RMS are based on estimates and our current knowledge and understanding of the disease. These estimates are typically based on one- on- one and group interactions with target physicians and other sources available at the time we make the estimates, including the scientific literature, healthcare utilization databases and market research. Although we believe our estimates are reasonable, many factors may limit their accuracy. For example, the sources we use to make the estimates may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases and the number of patients **affected** may turn out to be lower than expected. The total addressable market opportunity for BRIUMVI and our product candidates, if approved, ultimately depends upon, among other things, the approved prescribing information, acceptance by the medical community, patient access, and drug pricing and reimbursement. The number of patients in major markets, including the number of addressable patients in those markets, may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, new patients may become increasingly difficult to identify or gain access to, patients and physicians may choose to utilize competitive products or reimbursement may be unfavorable, all of which would adversely affect our results of operations and our business. We face substantial competition, which may result in others commercializing drugs before or more successfully than we do **,** resulting in the reduction or elimination of our commercial opportunity. We operate in a highly competitive segment of the biotechnology and biopharmaceutical market. We face competition from numerous sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and commercialization resources. Large pharmaceutical companies have extensive experience commercializing products and may have significant existing relationships with customers and more resources available to them to promote their products. Many are active in the same diseases that we are, including within the neurological and immunological fields, some in direct competition with us. We may also compete with these organizations to recruit commercial and other key personnel. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are more effective, have fewer or less severe side effects, are more convenient or are priced or

contracted differently than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. In a competitive environment, a company' s communications may also be subject to heightened scrutiny from regulators and competitors ~~,~~ under laws, regulations, and guidance about promotional communications (advertising and promotional labeling) and non- promotional communications (e. g., certain educational and scientific exchange) ~~;~~ **,** and with regard to potential competitor actions under federal law (**such as** the Lanham Act) and congruous state law, which protect businesses against the unfair competition of misleading advertising or labeling. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic or biosimilar competition and the availability of reimbursement from government and other third- party payors. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. These developments may render our product or product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater: ● research and development resources, including personnel and technology; ● regulatory experience; ● pharmaceutical development, clinical trial and pharmaceutical commercialization experience; ● experience and expertise in exploitation of intellectual property rights; and ● capital resources. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites, patient registration for clinical trials, and in identifying and in- licensing new products and product candidates. BRIUMVI, as well as any products that we are able to commercialize in the future, may become subject to unfavorable pricing regulations or third- party payor coverage and reimbursement policies, which would harm our business. The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the drug candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the drug candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products, even if more of our product candidates obtain marketing approval. Eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our costs and may not be made permanent ~~. On April 27, 2023, we received a product- specific J- Code for BRIUMVI (J2329), which became effective July 1, 2023 and is expected to help reduce reluctance by physicians to prescribe BRIUMVI based on reimbursement concerns~~ . However, some third- party payors may nevertheless still require documented proof that patients meet certain eligibility criteria in order to be reimbursed for BRIUMVI. Our ability to commercialize any product successfully also will depend in part on the extent to which coverage and reimbursement for our products and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement and co- payment levels. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by restricting coverage and limiting the amount of reimbursement for particular drugs. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs, examining the cost effectiveness of drugs in addition to their safety and efficacy. Third- party commercial payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Payors may restrict coverage of some products by using formularies under which only selected drugs are covered, variable co- payments that make drugs that are not preferred by the payor more expensive for patients, and utilization management controls, such as requirements for prior authorization or failure first on another type of treatment. Payors may target higher- priced drugs for imposition of these obstacles to coverage, and consequently our products may be subject to payor- driven restrictions. Additionally, in countries where patients have access to insurance, as in the U. S., insurance co-payment amounts or other benefit limits may represent a barrier to obtaining or continuing use of our products that receive regulatory approval. If we are unable to obtain or maintain coverage, or coverage is reduced in one or more countries, our product sales may be lower than anticipated and our financial condition could be harmed. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices. In the United States, for example, we must offer discounted pricing or rebates on purchases of pharmaceutical products under various federal and state healthcare programs, such as the Medicaid Drug Rebate Program, the 340B drug pricing program and the Medicare Part D Program. We must also report specific prices to government agencies under healthcare programs, such as the Medicaid Drug Rebate Program and Medicare Part B. The calculations necessary to determine the prices reported are complex and the failure to report prices accurately may expose us to penalties. If we are unable to expand our commercialization operations, we may not be successful in commercializing BRIUMVI or any product candidate, if and when such product candidates are approved, and we may not be able to generate revenue. Commercialization of pharmaceutical products is an extremely complex and highly capital and resource- intensive process. Even for established companies with existing infrastructure and significantly greater resources than we have, challenges have occurred. We have made and continue to make significant investments in our commercial organization and infrastructure. We ~~built~~ **have developed and expanded our** processes and systems to support the **ongoing** commercialization of BRIUMVI following its commercial launch **in the U. S.** on January 26, 2023. There are risks

involved with ~~establishing~~ **developing and expanding** our own commercialization capabilities. For example, if we are unable to recruit and retain adequate numbers of effective personnel to support the ongoing commercialization of BRIUMVI, we may not be successful in marketing and selling the product. Additional factors that may inhibit our efforts to **support the ongoing** ~~commercialize~~ **commercialization of** BRIUMVI and our other product candidates on our own, or through partnership, and generate product revenues include: ● the costs and time associated with the initial and ongoing training of commercialization personnel on the applicable disease states, products, competitors, and legal and regulatory compliance matters; ● the inability of commercialization personnel to obtain access to physicians or to effectively promote or provide education about BRIUMVI and any future approved products; ● the lack of complementary drugs to be offered by the Company, which may put us at a competitive disadvantage relative to companies with more extensive product lines; ● decisions by third- party payors to deny reimbursement of or delay coverage decisions regarding BRIUMVI or following approval of any product candidates; ● our inability to maintain a healthcare compliance program including effective mechanisms for compliance monitoring; ● our inability to establish and maintain commercial partnerships outside the U. S.; ● our inability, or the inability of a third party with whom we have partnered, to maintain the necessary regulatory approvals required to operate in markets outside of the U. S.; ● the timing of product availability for commercial sale following approval and continued product supply; and ● unforeseen costs and expenses associated with creating a commercialization organization. In addition, we have entered into a ~~commercialization~~ **Commercialization** ~~agreement~~ **Agreement** , and may enter into additional agreements in the future, that facilitate commercialization of BRIUMVI and / or future products that receive approval in markets outside the U. S. through partnerships **. On February 26, 2024, BRIUMVI was first made available in the European market by Neuraxpharm in Germany and is now commercially available in several other countries in the European Union and the United Kingdom** . However, there are also risks with entering into these types of arrangements with third parties to perform sales, marketing and distribution services. For example, we may not be able to enter into such arrangements on terms that are favorable to us. Our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any products or product candidates that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product or product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected. We believe there is potential market opportunity for BRIUMVI outside of the U. S., including in the EU. We have entered into a ~~commercialization~~ **Commercialization** ~~agreement~~ **Agreement** for the sale of BRIUMVI in certain territories outside the U. S., Canada and Mexico, the commercialization rights for which had been previously retained by TG, thus excluding certain Asian countries subject to previously existing partnerships, and we also may enter into certain collaboration and / or commercialization agreements with third parties in the future to facilitate market expansion. To the extent we do expand into other markets outside of the U. S. in which we are responsible for building and maintaining a commercial infrastructure, we expect to incur significant expenses in establishing an infrastructure to commercialize our drug products. Depending on the expenses incurred, it could have a negative impact on our cash resources. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any drug candidates that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and an even greater risk in connection with the commercialization of BRIUMVI and any other products for which we may receive marketing authorization in the future. If we cannot successfully defend ourselves against claims that BRIUMVI or any of our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any products that we may commercialize; ● injury to our reputation and significant negative media attention; ● withdrawal of clinical trial participants; ● significant costs to defend the related litigation, including the risk that any individuals who may face such related litigation may in turn seek to recover from us; ● substantial monetary awards to trial participants or patients; ● loss of revenue; and ● the inability to commercialize any products or product candidates that we may develop. Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive **and difficult to obtain and maintain** . We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise **. Any contracts that we enter into with government entities may involve future funding and compliance risks. Any contracts that we enter into with government entities may involve future funding and compliance risks. Such contracts with government entities are generally subject to risks such as lack of funding and compliance with unique requirements. For example, government contract purchase obligations are typically subject to the availability of funding, which may be eliminated or reduced. In addition, the future volume of products or services purchased by a government customer is often uncertain. Any of our government contracts might not be renewed or might be terminated for convenience with little prior notice. Contracts with government entities are typically subject to procurement laws that include socio- economic impacts, employment practices, environmental protection, recordkeeping and accounting obligations, and other requirements. These contractual and legal requirements could complicate our business and increase our compliance burden. The occurrence of any of these risks could harm our reputation and might have a materially adverse impact on our business operations, financial position and / or results of operations** . Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant operating losses since our inception, and we may incur losses in the future. Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in January 2012. To date, our operations have been limited primarily to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential drug candidates, undertaking ~~pre- clinical~~ **preclinical** studies and clinical trials, commercializing UKONIQ (withdrawn from sale) and launching and commercializing BRIUMVI. We are transitioning from a company with a research and

development focus and commercialization capabilities in oncology to a company capable of supporting commercial activities in ~~neurology and immunology in~~ the U. S. and outside the U. S. This transition involves a wide variety of risks, and we may not be successful in such transition. Since inception, we have focused our efforts and financial resources on clinical trials, manufacturing of our ~~product~~ **products** and product candidates **, establishing a commercial infrastructure** and preparing to support a commercial product. To date, we have financed our operations primarily through public offerings of our common stock and debt financing. Since inception, we have incurred significant operating losses. Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations, including our commercialization activities. **BRIUMVI is currently our only marketed product.** We expect to continue to incur significant **research and development** expenses **, as well as significant commercialization** and ~~operating~~ **outsourced manufacturing expenses as we continue to commercialize BRIUMVI. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future** losses **, or** for ~~the foreseeable future~~ **how long we may continue to experience a net profit. We may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue** . Our prior losses ~~, combined with expected future losses,~~ have had ~~,~~ and will continue to have an adverse effect on our stockholders' deficit and working capital **should** ~~. BRIUMVI is currently our only marketed product. We expect to continue to incur significant research and development expenses, and~~ we **be** ~~expect to continue to incur significant commercialization and outsourced manufacturing expenses as we commercialize BRIUMVI. Because of the numerous risks and uncertainties associated with developing pharmaceuticals, we are~~ unable to **maintain profitability in** ~~predict the extent of any~~ future **periods** ~~losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue~~ . To become and remain profitable, we must succeed in developing (or in- licensing) and commercializing our products or product candidates ~~that generate significant revenue~~ **, and continue to successfully commercialize BRIUMVI** . It is uncertain when and if we will **generate or continue to** generate any significant revenue from the sale of our product or any product candidates, if approved, in the future. Furthermore, no assurance can be given that we will meet revenue **and operating expenses** projections or guidance with respect to BRIUMVI or our product candidates, if approved. To obtain significant and sustained revenues and meet our revenue **and operating expenses** projections or guidance, we must succeed, either alone or with others, in (i) obtaining and maintaining regulatory approval for our ~~product~~ **products** and product candidates; and (ii) manufacturing ~~and~~ **,** marketing **and selling** our product and product candidates. Our ability to generate sustained revenue depends on a number of factors, including, but not limited to, our ability to: ● successfully complete clinical trials that meet their clinical endpoints; ● initiate and successfully complete all safety, pharmacokinetic, biodistribution, and non- clinical studies required to obtain U. S. and foreign marketing approval for our product and product candidates; ● obtain approval from the FDA and foreign equivalents to market and sell our product and product candidates, and maintain FDA **, MHRA** and EMA approvals of BRIUMVI for RMS; ● establish and maintain commercial manufacturing capabilities with third parties that are satisfactory to the regulatory authorities, cost effective, and that are capable of providing commercial supply of our product and product candidates; ● expand on our commercialization infrastructure to commercialize BRIUMVI, and / or entering into collaborations with third parties; **● obtain, develop, maintain, protect, and defend our intellectual property portfolio;** and ● achieve market acceptance of BRIUMVI and any other products for which we may receive regulatory approval in the medical community and with third- party payors. If we are unable to generate significant and sustained revenues, we will not become **or remain** profitable and we will be unable to continue our operations without continued funding. While we do not expect to need to raise additional capital, we may need to do so. If we are unable to raise capital, if needed, we may be required to delay, limit, reduce or eliminate some of our drug development programs or commercialization efforts. The development of pharmaceuticals is capital- intensive. We are also continuing to generate additional clinical data for BRIUMVI to support and potentially expand commercial adoption, including assessing long- term tolerability in ~~an~~ **our** Open- Label Extension of the Phase 3 ULTIMATE I and II trials and Phase 4 clinical studies necessary to satisfy post- approval commitments for regulatory authorities or those undertaken voluntarily by the Company to evaluate the use of BRIUMVI in alternate settings or with alternate methods of administration. Moreover, ~~now that~~ we ~~have launched~~ **expect to continue to incur significant research and development expenses, as well as significant commercialization and outsourced manufacturing expenses as we continue to commercialize** BRIUMVI ~~, we will need to expend substantial resources on maintaining approvals and continuing commercialization, manufacturing and distribution~~ over the foreseeable future. Additionally, **in 2025,** we expect to commence a **pivotal program evaluating a self- administered subcutaneous BRIUMVI product with an improved dosing frequency, commence pivotal trials aimed at further optimizing intravenous BRUIMVI for patients with RMS, evaluate BRIUMVI in other autoimmune diseases outside of MS and commence a Phase 1 clinical** trial evaluating azer- cel **for the treatment of primary progressive MS** ~~in autoimmune disease in 2024. We are also currently advancing our early- stage drug candidates, TG- 1701 and TG- 1801 in ongoing Phase 1 studies to identify tolerable and efficacious doses~~ . The amount and timing of our future funding requirements will depend on many factors, including, but not limited to, the following: ● the **timing and** success of the **ongoing** commercialization of BRIUMVI and any other products for which we receive regulatory approval; ● the costs and timing of clinical and commercial manufacturing supply arrangements for each product and product candidate; ● the costs of expanding our sales, distribution, and other commercialization capabilities; ● the costs and timing of regulatory approvals; ● the progress of our clinical trials, including expenses to support the trials and milestone payments that may become payable under our license agreements; ● our ability to establish and maintain strategic collaborations, including licensing and other arrangements; ● the costs involved in enforcing or defending patent claims or other intellectual property rights; and ● the extent to which we in- license or invest in other indications or product candidates. As a result, significant additional funding may be required. Additional sources of

financing to continue our operations in the future might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we could be forced to discontinue product development, reduce or forego commercialization efforts that are required for successful commercialization of BRIUMVI or any of our product candidates and otherwise forego attractive business opportunities. Any additional sources of financing may involve the issuance of our equity securities, which would have a dilutive effect to stockholders. Currently, other than BRIUMVI, our products are investigational and have not been approved by the FDA or any foreign regulatory authority for sale. For the foreseeable future, we will have to fund all our operations and capital expenditures from sales of BRIUMVI, cash on hand and amounts raised in future offerings or financings. Accordingly, our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in the early stages of commercial operations and the competitive environment in which we operate. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates and occupy valuable management time and resources. Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances, licensing agreements or other arrangements. We do not have any committed external source of funds, other than funds already borrowed under ~~the~~ **our term** loan ~~and security~~ **facility of $ 250 million pursuant to the financing** agreement **, dated August 2, 2024,** that we entered into with ~~Hercules in February 2019~~ **Blue Owl Capital Corporation** , **as administrative agent** ~~amended and restated in December 2021 and amended on March 31~~ , ~~2023~~ **HealthCare Royalty and Blue Owl Capital (the Financing Agreement)** (see Note 7 to our consolidated financial statements for more information). To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. We may also seek funds through collaborations, strategic alliances or licensing arrangements with third parties at a time that is not desirable to us and we may be required to relinquish valuable rights to some intellectual property, future revenue streams, research programs or products and product candidates or to grant licenses on terms that may not be favorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, which could limit our ability to expand our business operations and could harm our overall business prospects. Additionally, fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our drug candidates. Dislocations in the financial markets have generally made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. Moreover, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. Due to limited resources, we may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success. Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for a product candidate could be inaccurate, and our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing, sale or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. If any of the aforementioned events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations. ~~In February 2019~~ **On August 2** , ~~we entered into a Loan and Security Agreement, with Hercules Capital, Inc., a Maryland corporation (Hercules), and on December 30, 2021~~ **2024** ~~(the Amendment Closing Date)~~ , the Company entered into ~~an Amended and Restated~~ **a term loan facility of $ 250 million (the Initial Term** Loan ~~and Security Agreement (the Amended Loan Agreement~~) with ~~Hercules~~ **Blue Owl Capital Corporation, as administrative agent, HealthCare Royalty and Blue Owl Capital** . ~~Under the Amended~~ **The Initial Term** Loan **is governed by the Financing** Agreement, ~~Hercules increased~~ **which provides for (i) a single draw of** the **Initial Term Loan on the Closing Date and (ii) an uncommitted additional facility in an** aggregate principal amount of ~~the loan, available at the Company' s option, from~~ $ **100** ~~60. 0~~ million ~~to $ 200. 0 million. On March 31, 2023 (the First Amendment Effective Date), the Company entered into a First Amendment to the Amended Loan Agreement (the First Amendment) with Hercules. An advance of $ 25. 0 million was drawn at the First Amendment Effective Date~~ (see Note 7 to our consolidated financial statements for more information). ~~We have the option to request additional loan advances in an aggregate principal amount of up to $ 85. 0 million under the First Amendment.~~ All obligations under the **Financing** ~~Amended Loan~~ Agreement ~~, as amended,~~ are secured by **a lien on** substantially all **of** ~~our existing property and~~ assets ~~, excluding intellectual property~~ **of the Company and certain of our subsidiaries as guarantors** . This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing its outstanding debt obligations at

maturity. This indebtedness could also have important negative consequences, including: **To the extent additional debt is added to our current debt levels, the risks described above could increase, including in the ways described below:** ● we will need to repay the indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities; and ● our failure to comply with the restrictive covenants in the **Financing** ~~Amended Loan~~ Agreement ~~, as amended,~~ could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and ~~Hercules~~ **the creditors under the Financing Agreement** could seek to enforce its security interest in the assets securing such indebtedness. To the extent additional debt is added to our current debt levels, the risks described above could increase. We may not have cash available in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due. Failure to satisfy our current and future debt obligations under the **Financing** ~~Amended Loan~~ Agreement ~~, as amended,~~ , or the breach of any of its covenants, subject to specified cure periods with respect to certain breaches, could result in an event of default and, as a result, ~~Hercules~~ **Blue Owl Capital and HealthCare Royalty** could accelerate all the amounts due. In the event of an acceleration of amounts due under the **Financing** ~~Amended Loan~~ Agreement ~~, as amended~~ , as a result of an event of default, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time of such acceleration. In that case, we may be required to delay, limit, reduce or terminate our product candidate development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. ~~Hercules~~ **Blue Owl Capital Corporation** could also exercise its rights as ~~collateral~~ **the Administrative** ~~agent~~ **Agent** to take possession and dispose of the collateral securing the term loan for its benefit, which collateral includes substantially all **of** our ~~property other than intellectual property~~ **assets and certain of our subsidiaries as guarantors** . Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events. ~~The Amended Loan~~ **In addition, the Financing** Agreement ~~, as amended,~~ imposes operating and other restrictions on the Company. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things **(subject to the exceptions provided for in the Financing Agreement)** : ● dispose of certain assets; ● change its lines of business; ● engage in mergers, acquisitions **, joint ventures** or consolidations; ● incur additional indebtedness; ● create liens on assets; ● pay dividends and make contributions or repurchase our capital stock; and ● engage in certain transactions with affiliates. The breach of any of these restrictive covenants could have a material adverse effect on our business and prospects. Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail. **We** ~~On March 10, 2023, the Federal Deposit Insurance Corporation (FDIC) announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation, and on March 12, 2023, Signature Bank was closed by the New York State Department of Financial Services, and the FDIC was named receiver. Although we did not maintain any bank accounts with Silicon Valley Bank or Signature Bank, we~~ regularly maintain cash balances at third- party financial institutions in excess of the FDIC insurance limit. Any failure of ~~a~~ **such** depository institution to return any of our deposits **upon a liquidation of such institution** , or any other adverse conditions in the financial or credit markets affecting depository institutions, could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. Risks Related to Drug Development and Regulatory Approval If we are unable to **maintain or** obtain ~~and maintain~~ regulatory approval for our product and product candidates and ultimately cannot successfully commercialize our product or product candidates, or experience significant delays in doing so, our business will be materially harmed. Our ability to generate revenues from product sales will depend largely on the successful commercialization of BRIUMVI. Each of our product candidates will require additional non- clinical or clinical development, regulatory approval, and sufficient clinical and commercial supply. The success of our development programs and achievement of regulatory approval of our product candidates will depend on several factors, including, among others, the following: ● successful completion of our clinical programs with positive results that support a finding of effectiveness and an acceptable safety profile of our product candidates in the intended populations within the timeframes we have projected; ● Investigational New ~~Drugs~~ **Drug Applications** (INDs) and clinical trial applications (CTAs), being cleared **/ issued** / approved such that our product candidates can commence clinical trials; ● successful initiation and completion of preclinical studies and successful initiation of, enrollment in, and completion of clinical trials; ● sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; ● receipt of regulatory approvals from applicable regulatory authorities for our product candidates; ● establishing commercially viable arrangements with third- party manufacturers for clinical supply and commercial manufacturing; and ● obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in our clinical programs and regulatory submission timelines and may not be able to obtain regulatory approval for our product candidates. Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials or receive regulatory approval. Moreover, interim, " top- line, " and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be negatively impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed. Pharmaceutical development has inherent risks. The outcome of preclinical development testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Once a product candidate has displayed sufficient preclinical data to warrant clinical investigation, we will be required to demonstrate, through adequate and well- controlled clinical trials, that our product candidates are effective with a favorable benefit- risk profile for use in populations for their target indications before we can seek regulatory approvals for their commercial sale. Many drug

candidates fail in the early stages of clinical development for safety and tolerability issues or for insufficient clinical activity, despite promising ~~pre- clinical~~ **preclinical** results. Accordingly, no assurance can be made that a safe and efficacious dose can be found for these compounds or that they will ever enter into advanced **or pivotal** clinical trials alone or in combination with other product candidates. Moreover, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later- stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials. Individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. In addition, larger scale Phase 3 studies, which are often conducted internationally, are inherently subject to increased operational risks compared to earlier stage studies, including the risk that the results could vary on a region to region or country to country basis, which could materially adversely affect the outcome of the study or the opinion of the validity of the study results by applicable regulatory agencies. From time to time, we may publicly disclose top- line or preliminary data from our clinical trials, which is based on a preliminary analysis of available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of such data, and we may not have received or had the opportunity to fully and carefully evaluate all data **, such as later data,** from the particular study or trial, including all endpoints and safety data. As a result, top- line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Top- line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline, interim, or preliminary data we previously published. When providing top- line results, we may disclose the primary endpoint of a study before all secondary endpoints have been fully analyzed. A positive primary endpoint does not translate to all, or any, secondary endpoints being met. As a result, top- line and preliminary data should be viewed with caution until the final data are available, including data from the full safety analysis and the final analysis of all endpoints. Further, from time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. For example, time- to- event based endpoints such as duration of response (DOR) and progression- free survival (PFS), and continuously observed data such as annualized relapse rate (ARR) have the potential to change with longer follow-up. In addition, as patients continue on therapy, there can be no assurance ~~given~~ that the final safety data from studies, once fully analyzed, will be consistent with prior safety data presented, will be differentiated from other similar agents in the same class, will support continued development, or will be favorable enough to support regulatory approvals for the indications studied. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. The information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and regulators or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top- line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions we have reached, our ability to obtain approval for, or successfully commercialize, our product or product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Many of the results reported in our early clinical trials rely on local investigator-assessed efficacy outcomes which may be subject to greater variability or subjectivity than results assessed in a blinded, independent, centrally reviewed manner, often required of later phase, adequate and well- controlled registration- directed clinical trials. If the results from our registration- directed trials are different from the results found in the earlier studies, we may need to terminate or revise our clinical development plan, which could extend the time for conducting our development program and could have a material adverse effect on our business. Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete ~~pre- clinical~~ **preclinical** studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. It is impossible to predict when or if our product candidates will prove effective and safe in humans, will receive regulatory approval or will have a differentiated safety and tolerability profile. A failure of one or more clinical trials can occur at any stage of testing. Accordingly, our ongoing trials and future clinical trials may not be successful. Even if our clinical trials produce positive results, there can be no guarantee that the positive outcomes will be replicated in future studies either within the same indication as previously evaluated or in alternate indications and settings **, or that even with such replication marketing approval will be granted** . Successful completion of our clinical trials is a prerequisite to submitting a New Drug Application (NDA) or a Biologics License Application (BLA) to the FDA and a Marketing Authorization Application (MAA) to the EMA for each product candidate and, consequently, the ultimate approval and commercial marketing of our product candidates. We do not know whether any of our ongoing or future clinical trials for our product candidates will be completed on schedule, if at all. Whether or not **,** and **if so,** how quickly **,** we complete clinical trials depends in part upon the rate at which we are able to engage clinical research / trial sites and, thereafter, the rate of enrollment of patients, and the rate at which we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and

whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same diseases that we are studying. We may experience unforeseen events ~~, such as the COVID- 19 pandemic,~~ that could delay or prevent our ability to complete current clinical trials, initiate new trials, receive marketing approval or commercialize our product candidates, including: ● the FDA or other regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial; ● the FDA or other regulatory authorities or institutional review boards (IRBs) or **Data Safety Monitoring Boards (DSMBs) or** ethics committees (ECs) may not authorize us or our investigators to commence **or continue** a clinical trial or conduct a clinical trial at a prospective trial site or in a country; we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations (CROs), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional ~~pre- clinical~~ **preclinical** studies or clinical trials or we may decide to abandon drug development programs; ● the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, and enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post- treatment follow- up at a higher rate than we anticipate; ● our third- party contractors, including our clinical trial sites, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; ● we may elect to or regulatory authorities or IRBs **, DSMBs** or ECs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; ● the cost of clinical trials of our product candidates may be greater than we anticipate **; ● any shifts in the regulatory focus of the U. S. government as a reflection of changing administrations** ; ● the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including, without limitation, as a result of disruptions to our supply chains caused by global health crises, ~~such as the COVID- 19 pandemic,~~ international conflicts **in** ~~such as the Russian~~ **Russia and** ~~invasion of~~ Ukraine ~~or~~ **and** the **Middle East** ~~Israel- Hamas war~~ , economic instability, or natural disasters; ● regulatory authorities may revise the requirements applicable to our product candidates, or such requirements may not be as we anticipate; and ● our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities, IRBs **, DSMBs** or ECs to suspend or terminate the trials, or reports may arise from ~~pre- clinical~~ **preclinical** or clinical testing of other therapies in the same or a similar class that raise safety or efficacy concerns about our product candidates. We also could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the ~~Data and Safety Monitoring Board (~~ DSMB ~~)~~ for such trial or by the FDA or other regulatory authorities. Such regulatory authorities may impose a **clinical hold,** suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities ~~resulting in the imposition of a clinical hold~~ , unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition to the FDA, **the IRB and / or** the DSMB for our clinical trials may recommend modification to the study design or closure of the study entirely based on the **IRB' s and / or** DSMB' s interpretation of the benefit- risk of the study. While we develop charters that guide the nature of the **IRB and** DSMB meetings, their analysis and interpretation of study data occurs independently from us and is wholly within their control. Even if the **IRB or** DSMB finds no safety concerns and recommends no modifications to the ongoing study, this does not mean the safety profile reported in the study may support a marketing approval or commercial acceptance if marketing approval is granted. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Negative or inconclusive results from the clinical trials we conduct, unanticipated adverse medical events, or changes in regulatory policy could cause us to have to delay, repeat or terminate the clinical trials. If we are required to repeat or conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: ● be delayed in obtaining marketing approval for our product candidates; ● not obtain marketing approval at all; ● obtain marketing approval in some countries and not others; ● obtain **marketing** approval for indications or patient populations that are not as broad as intended or desired; ● be subject to post- marketing requirements or post- marketing commitments; ● be subject to increased pricing pressure; or ● have the drug removed from the market after obtaining marketing approval. In addition, changes in regulatory policy could cause us to have to repeat or conduct additional clinical trials or change our clinical development strategy ~~. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other " pivotal study " of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late- stage clinical trials of FDA- regulated products. If we are not able to adhere to these new requirements, our ability to conduct clinical trials may be delayed or halted~~ . Our drug development costs will also increase if we experience delays in testing or regulatory approvals. Certain clinical trials are designed to continue until a pre- determined number of events have occurred in the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower- than- expected event rates. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. Any delays in our ~~pre- clinical~~ **preclinical** or future clinical development programs may harm our business, financial

condition and prospects significantly. We may also incur additional costs if enrollment is increased. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site or the FDA' s acceptance of such data, may be jeopardized. Biologics carry unique risks and uncertainties, which could have a negative impact on our business. The successful development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited, and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture. Failure to successfully ~~,~~ develop, manufacture and sell BRIUMVI **or other biological product candidates we may develop** could adversely affect our business. Our product or product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or impact their availability and commercial potential after approval. Unexpected or undesirable adverse events caused by BRIUMVI or any of our product candidates that we take into clinical trials could cause either a DSMB or regulatory authorities to interrupt, delay, modify or suspend clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Even if a product candidate has obtained marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. This could prevent us from commercializing the affected product candidate and generating revenues from its sale. As is the case with all drugs, it is likely that there will be side effects associated with the use of our drug candidates. Results of our trials could reveal a higher than expected and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to discontinue an ongoing trial or deny approval of our drug candidates for any or all targeted indications. The drug- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, data may emerge, from confirmatory or other post- marketing studies, or from pharmacovigilance reporting, as products are used more widely, or for a longer duration, after approval that may affect the commercial potential of our products. Any of these occurrences may harm our business, financial condition and prospects significantly. Many compounds that initially showed promise in early- stage testing have later been found to cause side effects that prevented further development of the compound. Further, early clinical trials by their nature utilize a small sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and serious side effects of our drug candidates may only be uncovered when a significantly larger number of patients are exposed to the drug candidate in Phase 3 or registration- directed trials or when the drug candidate is on the market. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain marketing approval and generate revenues from its sale, or even if approved for sale may lack differentiation from competitive products, which could have a material adverse impact on our business and operations. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of BRIUMVI or our other product candidates may only be uncovered with a significantly larger number of patients exposed to the product. Any products or product candidates we may advance through clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals. The clinical development, manufacturing, labeling, packaging, storage, record- keeping, advertising, promotion, import, export, marketing and distribution, and pharmacovigilance and adverse event reporting of our product or product candidates or any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable regulatory authorities worldwide. In the United States, we are not permitted to market a **new** product candidate until we receive approval of a BLA or NDA from the FDA. The process of obtaining a BLA or NDA approval is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, approval policies or regulations may change over time. If we fail to gain approval to commercialize our product candidates from the FDA and other foreign regulatory authorities in the timelines we project or at all, we may be unable to generate the revenues that we may project or generate revenues at levels sufficient to sustain our business. The FDA and foreign regulatory authorities ~~have complete~~ **exercise extensive** control over the pharmaceutical product approval process, including substantial discretion to delay, limit or deny approval of a product candidate for many reasons. During the regulatory review process, the FDA or other regulatory authorities may disagree with or not accept our clinical trial design, may have questions about the potential impact of our study design on conclusions that can be drawn from the data, may interpret results differently than we do, may apply the results of our trials in one disease to the review of a regulatory application for a different disease even if the doses and therapeutic areas are distinct, and may change its view on the criteria that must be met for approval. This could happen even for a protocol used to support a trial that is subject to ~~an~~ **a Special Protocol Assessment (** SPA **)** agreement with the FDA. There is no guarantee that the FDA will not delay, limit or deny approval of our product candidates in the future. Furthermore, some of our clinical trials may be conducted as open- label studies, meaning that trial participants, investigators, site staff, some employees of our CROs, and our field- level employees (e. g., clinical research associates and monitors), among others, have knowledge of treatment arm assignments on a patient- level, which has the potential to introduce bias into study conduct. Further, even when our clinical trials are double- blind, double-dummy studies, unblinding of treatment arm assignment may occur from time to time, for example, on the occurrence of unexpected safety events which may necessitate understanding of study treatment. While we believe we have put in place adequate firewalls to prevent inappropriate unblinding of study data consistent with standard industry practice for these types of

studies, no assurance can be given that issues related to study conduct will not be raised. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the study design or data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee in evaluating (among other things) clinical data and safety and effectiveness considerations prior to making its final decision. These issues could cause a delay in the FDA' s review, lead the FDA to deny approval, or lead the Company to withdraw a regulatory application. Other reasons that the FDA or regulatory authorities around the world may delay, limit or deny approval of a product candidate, include: ● we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is tolerable and effective for an indication; ● the FDA may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care or the patient population, is potentially different from that of the United States; ● the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ● we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ● the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies and / or clinical trials; ● the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other marketing authorization submission to obtain regulatory approval in the United States or elsewhere; ● the FDA or comparable foreign regulatory authorities may identify issues related to the manufacturing processes or facilities of third- party manufacturers with which we or our collaborators currently contract for clinical supplies and plan to contract for commercial supplies; during the course of review, the FDA or foreign regulatory authorities may raise issues and request or require additional preclinical, clinical, chemistry, manufacturing, and control (CMC), or other data and information, and the development and provision of these data and information may be time consuming. We may not be able to generate the data within the time period necessary to obtain approval within the established regulatory review timelines, such as by a **Prescription Drug User Fee Act (** PDUFA **)** goal date or at all to satisfy the FDA or foreign regulatory authorities; ● the approval processes of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; or ● interruptions or delays in the operations of the FDA and foreign regulatory authorities as a result of global health **crises, inadequate government funding, political conditions** or economic crises, ~~such as the COVID- 19 pandemic,~~ international conflict, or ~~national~~ **natural** disasters may negatively impact review, inspection, and approval timelines. Even if we succeed in obtaining regulatory approval for a product candidate, the FDA may require **, or we may commit to,** post- marketing studies, including additional clinical trials such as those necessary to assess drug interactions or activity of a product in specific populations, which may be costly. The outcomes of post- marketing studies may impact product labeling and therefore, there can be no guarantee that the product attributes contained in the initial prescribing information will be maintained as future studies produce data. This includes, without limitation, additional results from studies evaluating drug- drug interactions and patients with certain comorbidities that may restrict the use of an approved product in select populations or introduce dose modifications or contraindicated concomitant medications that have the potential to impact the utility of a product or its perceived product profile among prescribers. Post- marketing studies may also lead to the introduction of new warnings in the product prescribing information. The FDA may require adoption of a REMS program requiring prescriber training or a post- marketing registry or may restrict the marketing and dissemination of our products. Finally, failure to complete a post- marketing commitment by the applicable post- marketing milestone date may lead to withdrawal of the product or indication. Any requirements to conduct post- approval studies or fulfill special post- approval requirements could impact our ability to commercialize our product or product candidates and increase our costs **. We are currently focusing the majority of our efforts on maintaining approval, improving and commercializing BRIUMVI and developing azer- cel for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable. We are currently focusing the majority of our resources and efforts on maintaining approval, improving and commercializing BRIUMVI and developing azer- cel for particular indications. As a result, we may forego or delay the pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. If we do not accurately evaluate the commercial potential or target markets for BRIUMVI and azer- cel, we may relinquish valuable rights to our product candidates or programs through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate (s) or program (s)** . A Breakthrough Therapy or Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process. We may seek Breakthrough Therapy or Fast Track designation for some of our drug candidates. If a drug is intended for the treatment of a serious or life- threatening condition, and the drug demonstrates the potential to address an unmet medical need for this condition, the Sponsor may apply for Fast Track designation or Breakthrough Therapy designation, the latter of which has more significant requirements. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular drug candidate is eligible for such a designation, we cannot be sure that the FDA would decide to grant it. Even if we receive Breakthrough Therapy or Fast Track designation for a drug candidate, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A drug that receives Fast Track designation is eligible for more frequent interactions with the FDA, priority review if relevant criteria are met, and rolling submission of the BLA or NDA. Even if rolling review is allowed, there is no guarantee that the FDA will have commenced or completed review of the BLA or NDA modules submitted earlier in the rolling review process. Neither Breakthrough Therapy nor Fast Track designation guarantees Priority Review of an NDA or BLA ~~application~~ . We may seek orphan drug designation for some of our drug candidates. However, we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity. Regulatory

authorities in some jurisdictions, including the United States, the European Union, and the United Kingdom, may designate drugs for relatively small patient populations as orphan drugs. Under the U. S. Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages, and user- fee waivers. Orphan drug designations are required to be maintained through annual reporting and are subject to re- evaluation. Based on the evolving data and development plans for our product candidates and changing incidence and prevalence rates for our intended indications, there can be no guarantee that we will be able to successfully maintain orphan drug designations that we have for certain of our drug candidates or that we will be successful in obtaining orphan designation for other drug candidates in the future. Generally, if a product 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 FDA or EMA from approving another marketing application for the same drug or biologic for that time period. Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve another product that meets the definition of a " same drug " under 21 C. F. R. 316. 3 for the same condition if the FDA concludes 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. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA exercises its authority to revoke orphan drug designation, which it may do on a variety of grounds, including that the request contained an untrue statement of material fact or omitted material information, or that the drug in fact was not eligible for orphan drug designation. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we intend to seek orphan drug designation for our other drug candidates, we may never receive such designations. Even if we receive orphan drug designation for any of our drug candidates, there is no guarantee that we will enjoy the benefits of those designations or obtain orphan drug exclusivity. In addition, the U. S. Orphan Drug Act may be subject to amendments that could reduce the period of marketing exclusivity or change the qualifications for orphan drug designation, which could adversely impact our products or product candidates that have or may be eligible for orphan drug designation. We are conducting clinical trials and anticipate conducting additional clinical trials for our product and product candidates at sites outside the United States, and ~~the FDA may not accept data from~~ trials conducted in such locations or clinical trial activities in such locations may be impacted by political conditions, including international conflict. Many of our clinical trials utilize international clinical research sites. We work with what we believe are reputable CROs and clinical research sites in conducting our studies internationally. Nevertheless, there can be heightened challenges to monitoring and oversight of global clinical trials and sponsors are subject to the risk that fraud, misconduct, incompetence, unexpected patient variability and other issues affecting the reliability, quality, and outcome of studies. ~~The geographic variability of the COVID- 19 pandemic also introduces increased risk in the conduct of clinical research in certain countries and territories where vaccination rates and available standard of care anti- viral therapy varies significantly.~~ Such ~~problems~~ **challenges** , if they were to occur, could negatively impact trial results, and depending on the circumstances and scope of concerns could potentially even prevent a trial from being useful or acceptable for regulatory approval. If such events were to occur with respect to any of our trials (and in particular with respect to registration- directed studies), they would have a substantial negative impact on our business. In addition, our clinical studies with sites outside the United States may be adversely impacted by international conflict. ~~For example,~~ **The ongoing conflict** in ~~February 2022,~~ Russia **and** ~~initiated a full- scale military invasion of~~ Ukraine ~~. In~~ **and impact** ~~one~~ **on** ~~or both countries, as well as~~ neighboring countries ~~that may be impacted by this conflict~~ (e. g. Poland, Slovakia, Belarus, Georgia) ~~, we have~~ **may adversely affect** clinical trial sites for our RMS and / or oncology programs. While no clinical trials are ~~actively~~ **currently** enrolling patients in ~~these territories~~ **Russia or Ukraine** , there are a number of trial subjects in long- term treatment and follow- up. The political and physical conditions in Russia and Ukraine have disrupted our ability to supply investigational drug product to impacted sites; impacted patients' ability to partake in our clinical trials and our ability to gather data on those patients, including long- term follow- up data; and resulted in suspension of clinical trial activities at impacted sites. Furthermore, the United States and its European allies have imposed significant sanctions against Russia and Belarus, including regional embargoes, full blocking sanctions, and other restrictions targeting major Russian financial institutions. Specifically, such sanctions have included, among other things, a prohibition on doing business with certain Russian companies, officials, and oligarchs; a commitment by certain countries and the European Union to remove selected Russian banks from the Society for Worldwide Interbank Financial Telecommunications (SWIFT) electronic banking network that connects banks globally; and restrictive measures to prevent ~~the~~ **certain** Russian ~~Central Bank~~ **financial institutions** from undermining the impact of the sanctions. Our ability to conduct clinical trials in Russia, Belarus, Ukraine and elsewhere in the region may also become restricted under applicable sanctions laws. The conflict, as well as government responses, has resulted in global economic instability, which could affect our supply chain and commercialization efforts. While we **currently** do not believe this conflict will have a material impact on product development or our overall business, given the ~~rapidly~~ evolving situation and the **related geopolitical** ~~potential to expand beyond Ukraine~~ and ~~Russia~~ **economic uncertainties** , the full impact of the conflict remains uncertain **. The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their respective jurisdictions. We have been conducting, and may continue to conduct, clinical trials globally. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authorities from clinical trials conducted outside of their respective**

jurisdictions may be subject to certain conditions, which may include conditions related to the applicability and verifiability of the data and cooperation with foreign regulatory agencies. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan, and may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction . Approval of one of our product candidates in the United States would not assure approval of that candidate in foreign jurisdictions. We intend to seek additional product approvals in certain countries outside of the United States. The approval procedures for pharmaceuticals vary among countries and obtaining approval in one jurisdiction does not guarantee approval in another jurisdiction. For example, even if the FDA grants approval of a product candidate comparable regulatory authorities in foreign jurisdictions may not approve the same product candidate, or the same indications for use for the product candidate, or may require additional evidence for approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. In many countries outside the United States, the product must be approved for reimbursement before it can be marketed. As a general matter, however, the foreign regulatory approval process involves a lengthy and challenging process with risks similar or identical to the risks associated with the FDA approval discussed above. Therefore, we cannot guarantee that we, or future collaborators, will obtain approvals of our product and product candidates in any foreign jurisdiction on a timely basis, if at all. Failure to receive approval in certain foreign markets could significantly impact the full market potential of our product and product candidates and may negatively impact the regulatory process in other countries. Furthermore, if we obtain regulatory approval for a product or product candidate in a foreign jurisdiction, we will be subject to the burden of complying with complex regulatory, legal, and other requirements that could be costly and could subject us to additional risks and uncertainties. We have product candidates still under development and are also engaging manufacturing partners in commercial manufacturing activities, and as such clinical and commercial manufacturing site additions and process improvements implemented in the production of our product and product candidates may affect their timely delivery or quality. We have limited experience in manufacturing products for clinical or commercial purposes. We currently do not have any manufacturing capabilities of our own. We have established a contract manufacturing relationship for the commercial supply of BRIUMVI with Samsung Biologics. As with any supply program, obtaining materials of sufficient quality and quantity to meet the requirements of the market demand for BRIUMVI and our development programs cannot be guaranteed and we cannot ensure that we will be successful in these endeavors. To the extent possible and commercially practicable, we plan to develop back- up strategies for raw materials ~~,~~ **and** manufacturing and testing services for our commercial products. Given the long lead times and cost of establishing additional commercial manufacturing sites we expect that we will rely on single contract manufacturers to produce our commercial products under current Good Manufacturing Practice, or cGMP, regulations for ~~many~~ **the next several** years. Our commercial manufacturing partners have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and / or on a timely basis. ~~Both~~ **All** of these occurrences would be beyond our control. We expect to similarly rely on contract manufacturing relationships for our development programs and any products that we may in- license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all. Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration, if applicable, and corresponding state agencies to ensure strict compliance with cGMP requirements and other state and federal regulations. Where manufactured products are globally registered, similar regulatory inspection burdens are applicable from each and every marketed territory. If our manufacturing partners are inspected and deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped, and supplies could be delayed or otherwise disrupted. If we need to change manufacturers either before or after commercialization, the FDA and corresponding foreign regulatory agencies may need to approve these new manufacturers in advance, which will involve testing, regulatory submissions, and additional inspections to ensure compliance with FDA and other regulations and standards, and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all. Some of our product and product candidates are currently manufactured in relatively small batches for use in ~~pre- clinical~~ **preclinical** and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity and / or analytical profile of the product or product candidates, which may affect the safety and efficacy of the products. It is possible that additional and / or different adverse events may appear among patients exposed to drug product manufactured under one process compared to the other, or that adverse events may arise with greater frequency, intensity and duration among patients exposed to drug product manufactured under one process compared to the other. Further, no assurance can be given that the material manufactured from any future optimized processes, if any, for BRIUMVI or any of our product candidates will perform comparably to the product or product candidates as manufactured to date which could result in an unexpected safety or efficacy outcome as compared to the data published or presented to date. Similarly, following each round of process improvements, if any, for any of our drug candidates, future clinical trial results conducted with the new material will be subject to uncertainty related to the effects, if any, of those additional process improvements that were made. Risks Related to Governmental Regulation of Pharmaceutical Industry and Legal Compliance Matters We are subject to new legislation, regulatory proposals and third- party payor initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise

capital. In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes or proposed changes to the healthcare system, many of which have focused on prescription drug pricing and lowering overall healthcare costs, that could impact our ability to sell our products profitably and support future innovation. We expect prescription drug pricing and other healthcare costs to continue to be subject to intense political and social pressures on a global basis. In the United States, the President, federal and state legislatures, health agencies and third- party payors continue to focus on containing the cost of healthcare and addressing public concern over access and affordability of prescription drugs. The ~~Patient Protection and~~ Affordable Care Act, ~~as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) was enacted in 2010 and~~ made significant changes to the U. S. healthcare system **, which** ~~. ACA changes~~ included expanding healthcare coverage through Medicaid ~~expansion~~ and implementation of the individual health insurance mandate; changing coverage and reimbursement of drug products under **Medicare, Medicaid and 340B** government ~~healthcare~~ programs; imposing an annual fee on manufacturers of branded drugs; and expanding government enforcement authority. **The** ~~Although the~~ ACA has been the subject of ~~a number of~~ legislative and litigation challenges ~~since it passed, it is expected that the Biden Administration will seek to strengthen and expand the ACA~~ . We cannot predict **whether the new U. S. administration would impose any further changes to the ACA and** what effect, if any, ~~further~~ **such** changes to the ACA would have on our business. ~~Beyond the ACA, there has been increasing legislative, regulatory and enforcement interest with respect to prescription drug pricing practices. Proposals that may garner bipartisan legislative support or become legislation through reconciliation include adding a cap on out- of- pocket spending under Medicare Part D, authorizing Medicare to negotiate certain drugs covered by Medicare Parts D and B directly with manufacturers, and imposing limits on increases in drug prices. In addition, President Biden may take executive action to introduce new drug pricing models and other drug pricing initiatives. The Biden Administration also may propose substantial changes to the U. S. healthcare system, including expanding government- funded health insurance options.~~ We are uncertain of the impact or outcome of potential Executive Orders, rescission of rules and policy statements, or new legislation, **including the imposition of tariffs, that the new U. S. administration may impose,** especially **with regards to the healthcare regulatory and policy landscape, or the impact they may have on our business. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs, or** any ~~relative~~ **significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse** impact on ~~the healthcare regulatory and policy landscape, or~~ **our anticipated** ~~the impact they may have on our business. We expect drug pricing will continue to be a focus of the Biden Administration. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain~~ product **revenues** ~~access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing~~ . There have been several recent U. S. Congressional inquiries and proposed and enacted legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs ~~under Medicare, limit price increases, evaluate the relationship between pricing and manufacturer patient programs,~~ and reform government health care program reimbursement methodologies for prescription drugs. ~~For example~~ **In September 2024** , **CMS issued a final rule titled " Medicaid Program; Misclassification** ~~the Bipartisan Budget Act of 2018 (the BBA) increased manufacturer point- of- sale discounts off~~ **of** ~~negotiated prices of applicable brand drugs~~ **Drugs** ~~in~~ **, Program Integrity Updates Under** the ~~Medicare~~ **Medicaid** ~~Part D coverage gap from 50 % to 70 % effective as of January 1, 2019, ultimately increasing the liability for brand drug~~ **Drug** ~~manufacturers~~ **Rebate Program " which may impact our reimbursement and rebate strategy** . We expect that health care reform measures that may be adopted in the future, may result in ~~more rigorous coverage criteria,~~ increased manufactured financial liability and additional downward pressure on the price that we may receive for any of our product candidates, if approved. Any reduction in reimbursement from Medicare or other government health care programs may result in a similar reduction in payments from private payors. There continue to be efforts to lower drug prices through increased competition, with policy proposals seeking to facilitate generic and biosimilar approval and marketing authorization. For example, ~~in 2018,~~ the FDA ~~announced the~~ **' s** Biosimilar Action Plan and ~~sought input on how~~ **current Biosimilar User Fee Amendments provide a detailed account of** the agency ~~can best facilitate greater availability~~ **' s strategic priorities to improve the efficiency** of **the** biosimilar **and interchangeable** ~~products~~ **product development** ~~, including input on whether changes to an~~ **and** ~~approved~~ **approval process and support robust competition** ~~biologic (e. g., a new indication) would be protected by the remainder of the statutory 12- year exclusivity period (commonly referred to as umbrella exclusivity)~~ . In the event there is a modification to the biologic exclusivity period **, other applicable regulatory exclusivity periods** or other steps taken to facilitate biosimilar ~~or generic~~ approvals, we could experience ~~biosimilar / generic~~ competition ~~of~~ **to** any products for which we receive FDA approval at an earlier time than currently anticipated. **The IRA included** ~~Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the Act), which~~ , among other provisions, ~~included~~ several measures intended to lower the cost of prescription drugs and related healthcare reforms. **Among** ~~Specifically, the~~ **other things,** ~~Act authorizes and directs~~ the ~~Department~~ **IRA requires manufacturers** of **certain** ~~Health and Human Services (DHHS) to set drug~~ **drugs to engage in** price ~~caps for certain high- cost~~ **negotiations with Medicare beginning in 2026, imposes rebates under** Medicare Part B and ~~Part D qualified drugs, with the initial list of drugs selected on August 29, 2023, and the first year of maximum price applicability to begin in 2026. On October 3, 2023, the Centers for Medicare & Medicaid Services announced that all manufacturers of the initially selected drugs opted to participate. The Act further authorizes the DHHS to penalize pharmaceutical manufacturers that increase the price of certain Medicare Part B and Part D drugs faster than the rate of inflation. Finally, the Act creates significant changes to the~~ Medicare Part D ~~benefit design by capping~~ **to penalize price increases that outpace inflation, and replaces the** Part D **coverage gap discount program with a new discounting program** ~~beneficiaries' annual out- of- pocket spending at $ 2, 000~~ beginning in 2025. We cannot be sure whether additional or related legislation or rulemaking will be issued or enacted, or what impact, if

any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future. ~~At the state level, individual~~ **Individual** states are experiencing significant economic pressure within their respective Medicaid programs and responding to public concern over the cost of healthcare. States, including California, Florida, Nevada and Maine, among others, have responded to these pressures with a range of legislative enactments and policy proposals designed to control prescription drug prices by, for example, allowing importation of pharmaceutical products from jurisdictions outside the U. S., imposing **Prescription Drug Affordability Boards, some with the ability to impose** price controls on state drug purchases ~~, consolidating state drug purchasing to a single purchaser~~ , and imposing transparency measures around prescription drug prices and marketing costs. These measures, which vary by state, could reduce the ultimate demand for our products, if approved, or put pressure on our product **net** pricing ~~. In addition, other legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products' or product candidates' commercial success. More broadly, the Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through 2030 (except May 1, 2020 to December 31, 2020). Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenues~~ . Furthermore, legislative and regulatory proposals have been made to expand post- approval requirements, make changes the Orphan Drug Act and related guidance, reform the 340B Drug Pricing Program, and restrict sales and promotional activities for drugs. With respect to the 340B Drug Pricing Program **,** recent legislative proposals **,** as well as judicial challenges to DHHS' s policies **,** present both opportunities and challenges for drug manufacturers participating in the program. Further, we cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. **It is not possible at this time to determine whether changes in the administration may change the regulatory focus and / or implementation of any regulations, policies or reforms.** In many international markets, including the European Union, the government regulates prescription drug prices, patient access, and / or reimbursement levels to control the biopharmaceutical budget of their government- sponsored healthcare system. The European Union and some individual countries have announced or implemented measures and may in the future implement new or additional measures, to reduce biopharmaceutical costs to contain ~~the overall level of~~ healthcare expenditures. These measures vary by country and may include, among other things, non- coverage decisions, patient access restrictions, international price referencing, mandatory discounts or rebates, and cross- border sales of prescription drugs. These measures may adversely affect our ability to generate revenues or commercialize our product or product candidates in certain international markets. There likely will continue to be pressure on prescription drug prices globally and legislative and regulatory proposals, including at the federal and state levels in the U. S., directed at broadening the availability of health care and containing or lowering the cost of health care products and services. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, health insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect, among other things: ● our ability to generate revenues and achieve or maintain profitability; ● the demand for any products for which we may obtain regulatory approval; ● our ability to set a price that we believe is fair for our products; ● the level of taxes that we are required to pay; and ● the availability of capital. **Inadequate funding for the FDA, the SEC or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result.** In addition, ~~governments~~ **government** ~~may impose price controls,~~ **funding of the SEC and other government agencies on** which **our operations** may **rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also extend the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would** adversely affect our **business. For example, over the last several years, the U. S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to review and process our regulatory submissions in a timely matter, which could have a material adverse effect on our business. Further,** future ~~profitability~~ **government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations** . ~~Our~~ **Some of our** relationships with customers and third- party payors are subject to applicable fraud and abuse laws, false claims laws, transparency and disclosure laws, health information and security laws, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings. With the FDA ~~and~~ **,** EMA **and MHRA** approval of BRIUMVI, we are subject to additional extensive healthcare statutory and regulatory requirements and oversight by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third- party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our past, current and future relationships, arrangements and interactions with these professionals and entities, as well as with patients and patient advocacy organizations expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that

may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product and product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following: ● the federal Anti- Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. 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 **. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. This law applies to our marketing practices, educational programs, pricing policies and relationships with healthcare providers. We continue to evaluate what effect, if any, these rules will have on our business** ; ● the federal False Claims Act imposes 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, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. **For example, life sciences companies have faced enforcement actions under the False Claims Act in connection with their alleged off- label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product, among other activities.** In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute or the Federal Food, Drug, and Cosmetic Act (FDCA) constitutes a false or fraudulent claim for purposes of the False Claims Act; ● the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) **as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and its implementing regulations, has fraud provisions that** ~~imposes~~ **impose** criminal and civil liability for **knowingly and willingly** executing **, or attempting to execute,** a scheme to defraud any healthcare benefit program, **including private third- party payors,** or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation **. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs, or integrity oversight and reporting obligations to resolve allegations of non- compliance** ; ● the Physician Payments Sunshine Act under section 6002 of the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children' s Health Insurance Program to monitor and report certain information related to payments and other transfers of value to and the ownership and investment interests of physicians and certain other healthcare providers as well as teaching hospitals to the federal government for redisclosure to the public **. CMS has the potential to impose penalties for violations of the Physician Payments Sunshine Act, depending on the circumstances, and reported payments also have the potential to draw scrutiny to our relationships with health care practitioners and academic medical institutions, which may have implications under the Anti- Kickback Statute and other healthcare laws** ; ● HIPAA, as amended by **HITECH and** ~~the~~ **other amendments,** ~~Health Information Technology for Economic and Clinical Health Act of 2009~~ and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information **. HITECH created new tiers of civil monetary penalties, made civil and criminal penalties directly applicable to business associates, and gave state attorneys authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs** ; ● a wide range of federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers including those related to privacy; ● the FDCA and its implementing regulations, which among other things, strictly regulate drug product marketing and prohibit manufacturers from promotion and marketing of products prior to approval or for uses inconsistent with the FDA- required labeling; ● federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs; ● the Drug Supply Chain Security Act (DSCSA), which imposes obligations on entities in the commercial product supply chain, including manufacturers, to identify and track prescription drugs as they are distributed in the U. S.; and ● state law equivalents of some of the above federal laws, such as anti- kickback and false claims laws that may apply to items or services reimbursed by any third- party payor, including commercial insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, **marketing restrictions** and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts. As we continue commercialization of BRIUMVI, we are taking steps to provide patient support services to help patients access the product. Our patient support programs are administered in conjunction with a patient support program vendor and other third parties. There has been heightened ~~governmental~~ scrutiny ~~over~~ **by government enforcement agencies, including, by** the ~~scope~~ **U. S. Department** of **Health** ~~patient support programs~~ and **Human Services Office of Inspector General (OIG) and** the

~~manner~~ **U. S. Department of Justice (DOJ)** in ~~which~~ drug manufacturers **' product** and **patient assistance programs and** ~~their~~ -- **the** ~~vendors operate~~ **operation of** such programs **, including reimbursement support services, and investigations into these programs have resulted in significant civil and criminal settlements** . We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws, regulations, or evolving government guidance on patient support programs. A government investigation, regardless of its outcome, could impact our business practices, harm our reputation, divert attention of management, increase our expenses and reduce availability of assistance to patients. If we or our vendors are deemed to fail to comply with relevant laws, regulations or government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. The compliance and enforcement landscape, and related risk, is informed by government enforcement precedent and settlement history, Advisory Opinions, and Special Fraud Alerts. Our approach to compliance may evolve over time in light of these types of developments. Additionally, the potential safe harbors available under the federal Anti- Kickback Statute are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. If our operations, including activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government- funded healthcare programs, such as Medicare and Medicaid, qui tam actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations. If we violate applicable data privacy and security laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, reputation harm and the curtailment or restructuring of our operations. We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Within the United States, ~~various federal and state laws regulate the privacy and security of personal information and so may affect our business operations. For example, at the federal level, our operations may be affected by the data privacy and security provisions of~~ HIPAA, as amended by ~~the~~ **HITECH, establishes a federal " floor " with respect to privacy, security, and breach notification requirements as it pertains to protected** ~~Health~~ **health** ~~Information~~ **information** ~~Technology~~ **subject to HIPAA and does not supersede any state laws insofar as they are broader for** ~~-~~ **or** ~~Economic and Clinical Health Act and its implementing~~ **more stringent than HIPAA. There are numerous other laws,** regulations **and legislative and regulatory initiatives at the federal and state levels addressing privacy and security of personal data. Depending on the data we receive, we may be subject to federal and state privacy- related laws that may be more restrictive or contain different requirements than the privacy regulations issued under HIPAA. These laws vary and could impose additional penalties and requirements related to such data** . HIPAA affects the ability of healthcare providers and other entities with which we may interact, including clinical trial sites, to disclose patient health information to us. Under Section 5 (a) of the Federal Trade Commission Act (FTCA), the Federal Trade Commission (FTC) expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. **The FTC has asserted authority and issued enforcement actions in response to actual or perceived unfair or deceptive practices by a company in the handling of consumer information.** Medical data **, and health information more generally,** is considered sensitive data that merits stronger safeguards. States may also impose requirements. For example, the California Consumer Privacy Act **of 2018** (CCPA) **created** ~~, went into effect in January 2020 creating~~ data privacy obligations for covered companies and ~~providing~~ **provides** privacy rights to California residents, including the right to opt out of certain disclosures of their information. **The CCPA** ~~Colorado, Connecticut, Utah, Virginia and Iowa have~~ also ~~enacted~~ **created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The California Privacy Rights Act of 2020 (CPRA) significantly expanded the CCPA to grant additional rights to California residents and established a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Data privacy and cybersecurity are also areas of increasing state legislative focus. Among other things, these state- specific laws create new** data privacy **obligations for covered companies and provide new privacy rights to state residents, including the right to opt out of certain disclosures of their information. Draft regulations implementing certain of the state** statutes **have been published** . ~~and both California and Colorado~~ **but many questions remain as to how all of the new statutes will be interpreted. These laws** are ~~also undergoing~~ **rapidly changing, and tracking, analyzing and complying with such laws require significant time and expenses and can materially impact** ~~or~~ **our** ~~have undergone rulemaking procedures to finalize regulatory regimes to supplement~~ **business. We cannot predict where new legislation might arise,** ~~their~~ -- **the** ~~privacy~~ **scope of such legislation, or the potential impact to our business and operations. New federal and** ~~statutes~~ --- **state laws and regulations that may be enacted in the future may require us to modify our data processing practices and policies, incur substantial compliance- related costs and expenses, and otherwise suffer adverse impacts on our business** . Numerous other jurisdictions regulate the privacy and security of ~~personally~~ -- **personal** ~~identifiable~~ data. For example, the processing of personal data in the European Economic Area (EEA), is subject to the General Data Protection Regulation (GDPR) ~~, which took effect in May 2018~~ . The GDPR increases obligations with respect to clinical trials conducted in the EEA, such as in relation to the provision of fair processing notices, exercising data subject rights and reporting certain data breaches to regulators and affected individuals, as well as how we document our relationships with third parties that process GDPR- covered personal data on our behalf. The

GDPR also increases the scrutiny applied to transfers of personal data from the EEA (including from clinical trial sites in the EEA) to countries that are considered by the EC to lack an adequate level of data protection, such as the United States. In July 2020, the Court of Justice of the European Union invalidated the EU- U. S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U. S., which ~~decision~~ may lead to increased scrutiny on data transfers from the EEA to the U. S. generally and increase our costs of compliance with data privacy legislation. If **we experience a reportable data breach that is subject to any data privacy and security laws or if** our operations are found to **otherwise** be in violation of any data privacy and security laws, rules or regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines **, litigation** and the curtailment or restructuring of our operations, which could adversely affect our ability to operate our business **, our reputation** and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, rules or regulations, we cannot be certain that our program will address all areas of potential exposure and the risks in this area cannot be entirely eliminated, particularly because the requirements and government interpretations of the requirements in this space are constantly evolving. Any action against us for violation of these laws, rules or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business, as well as damage our business or reputation. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly. If we fail to adequately understand and comply with the local laws and customs as we expand into new international markets, these operations may incur losses or otherwise adversely affect our business and results of operations. We expect to operate a portion of our business in certain countries through subsidiaries or through supply, marketing, and distributor arrangements. In those countries where we have limited experience in operating subsidiaries and in reviewing equity investees, we will be subject to additional risks related to complying with a wide variety of national and local laws, including restrictions on the import and export of certain intermediates, drugs, technologies and multiple and possibly overlapping tax laws. In addition, we may face competition in certain countries from companies that may have more experience with operations in such countries or with international operations generally. We may also face difficulties integrating new facilities in different countries into our existing operations, as well as integrating employees hired in different countries into our existing corporate culture. If we do not effectively manage our operations in these subsidiaries and review equity investees effectively, or if we fail to manage our alliances, we may lose money in these countries, and it may adversely affect our business and results of our operations. In all interactions with foreign regulatory authorities and other government agencies, we are exposed to liability risks under the Foreign Corrupt Practices Act **(FCPA)** or similar anti- bribery laws **. We may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, or local anti- corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the U. S. and the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements, and currency exchange regulations, which we collectively refer to as Trade Control Laws. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti- corruption laws, including the FCPA, similar anti- bribery laws, or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, and other anti- corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC may also suspend or bar issuers from trading securities on U. S. exchanges, including the Nasdaq Stock Market, for violations of the FCPA' s accounting provisions. Likewise, any investigation of any potential violations of the FCPA, other anti- corruption laws or Trade Control Laws by the U. S. or other authorities, could also have an adverse impact on our reputation, our business, results of operations and financial condition** . Any product for which we obtain marketing approval, including BRIUMVI, could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with products. Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the indicated uses for which the drug may be marketed or to conditions of approval that may require potentially costly post- marketing clinical trials or surveillance to monitor safety and efficacy of the drug candidate. In addition, any product for which we obtain marketing approval, along with the manufacturing processes and facilities, post- approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of, and review by, the FDA, EMA and comparable regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding promotional interactions with healthcare professionals. Failure to comply with these regulatory requirements or later discovery of previously unknown problems with products, manufacturers, or manufacturing processes, may result in actions such as: ● restrictions on product manufacturing, distribution or use; ● restrictions on the labeling or marketing of a product; ● requirements to conduct post-marketing studies or clinical trials; ● warning letters or other advisory actions; ● request for withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we or our subsidiaries submit; ● recalls; ● suspension or termination of ongoing clinical trials; ● fines, restitutions, or disgorgement of profits or revenues; ● refusal to permit the import or export of products; ● product seizure or detentions; ● injunctions or the imposition of civil or criminal penalties; and ● adverse publicity. Any **internal or** government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA' s or EMA' s regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that

could prevent or delay regulatory approval of our product candidates or further restrict or regulate post- approval activities. We also cannot predict the likelihood, nature, or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we, or our respective suppliers, third- party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we, our subsidiaries, or our respective collaborators may be subject to the actions listed above, including losing marketing approval for products, resulting in decreased revenue from milestones, product sales or royalties. If we or any of our contract manufacturers and suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business. Our third- party manufacturers, suppliers, and we are subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, release, disposal of, and exposure to, hazardous and regulated materials. Violation of these laws and regulations could lead to substantial fines and penalties. Although we believe that our safety procedures, and those of our third- party manufacturers, for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations. In addition, we could become subject to potentially material liabilities relating to the investigation and cleanup of any contamination, whether currently unknown or caused by future ~~releases~~ **incidents. Our research and development activities could be affected or delayed as a result of shortages in animal availability or possible restrictions on animal testing. Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products. Certain laws and regulations may require us to test our product candidates on animals before initiating clinical trials involving humans. Failure to access or a significant delay in accessing animal research models that meet our needs or that fulfill regulatory requirements may materially adversely affect our ability to advance our preclinical and clinical programs and successfully develop our product candidates, which result in significant harm to our business. Additionally, animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed or become more expensive. The Animal Welfare Act (AWA), is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti- cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines, penalties and adverse publicity, and our operations could be adversely affected** . Risks Related to Our Dependence on Third Parties We rely on third parties to generate clinical, preclinical and other data necessary to support the regulatory applications needed to conduct clinical trials and submit for marketing approval. We rely on third parties to help conduct our planned clinical trials. If these third parties do not perform their services as required, we may not be able to obtain regulatory approval for or commercialize our product or product candidates when expected or at all. In order to submit an IND, BLA, or NDA to the FDA and maintain these applications, it is necessary to submit all information on the clinical, non- clinical, chemistry, manufacturing, controls and quality aspects of the product candidate. Clinical trial applications and marketing authorization applications for foreign regulatory bodies have substantially similar requirements. We rely on our third- party contractors and our licensing partners to provide portions of this data. If we are unable to obtain this data, or the data is not sufficient to meet the regulatory requirements, we may experience significant delays in our development programs and commercialization efforts. Additionally, we use CROs to assist in the conduct of our current clinical trials and expect to use such services for future clinical trials and we rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and appropriate regulations. Our current and future CROs, investigators and other third parties play a significant role in the conduct of our trials and the subsequent collection and analysis of data from the clinical trials. There is no guarantee that any CROs, investigators and other third parties will devote adequate time and resources to our clinical trials or perform as contractually required. If any third parties upon whom we rely for administration and conduct of our clinical trials fail to meet expected deadlines, fail to adhere to its clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated, and we may not be able to commercialize our product or product candidates. In addition to the third parties identified above, we are also heavily reliant on the conduct of our patients enrolled to our studies by our third- party investigators. We rely on our clinical trial sites and investigators to properly identify and screen eligible candidates for our clinical trials, and for them to ensure participants adhere to our clinical protocol requirements. The majority of our clinical trial conduct occurs in the outpatient setting, where patients are expected to continue to adhere to our study protocol specified requirements. The ability of our enrolled patients to properly identify, document, and report adverse events; take protocol specified study drugs at the correct quantity, time, and setting, as applicable; avoid contraindicated medications; and comply with other protocol specified procedures such as returning to the trial site for scheduled laboratory and disease assessments, is wholly out of our control. Deviations from protocol procedures, such as those identified previously, could materially affect the quality of our clinical trial data, and therefore ultimately affect our ability to develop and commercialize our drug candidates. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow- up information

on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. If any of our clinical trial sites is required by the FDA or IRB to close down due to data management or patient management or any other issues, we may lose clinical trial subjects. Whether conducted through a CRO or through our internal staff, we are solely responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or other enforcement actions that may include civil penalties or criminal prosecution. We and our CROs are required to comply with regulations, including GCP guidelines for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drug candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, clinical investigators, CROs, institutional review boards, and non- clinical laboratories. If we, our CROs, our investigators or other third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our current or future clinical trials comply with GCPs. In addition, our clinical trials must be conducted with drug candidates produced under cGMP regulations. Our failure or the failure of our CROs or **Contract Manufacturing Organizations (** CMOs **)** to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register most ongoing clinical trials and post the results of completed clinical trials on government- sponsored databases, e. g., ClinicalTrials. gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. CROs play an important role in the conduct of our clinical trials, especially outside of the United States. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct current or future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may: ● have staffing difficulties; ● fail to comply with contractual obligations; ● experience regulatory compliance issues; ● undergo changes in priorities or become financially distressed; or ● form relationships with other entities, some of which may be our competitors. These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our drug candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our drug candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct, and this could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product or product candidates. As a result, we believe that our financial results and the commercial prospects for our product or product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed. We contract with third parties for the manufacture **and testing** of BRIUMVI for commercial supply, as well as all of our clinical product supply, and we expect to continue to do so. This reliance on third parties increases the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture, testing, packaging and labeling of any products that we commercialize and our product candidates for ~~pre- clinical~~ **preclinical** development and clinical testing. For example, we currently rely on Samsung Biologics for clinical and commercial supply of BRIUMVI. In addition, we utilize multiple vendors who provide testing services. Our reliance on third parties increases the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. The facilities used by contract manufacturers to manufacture, test, package, and label our product and product candidates typically undergo periodic inspections by the FDA or a comparable foreign regulatory authority to verify compliance with applicable cGMP regulations. Additional inspections may be conducted after we submit our marketing applications to or receive marketing approval from the FDA or a comparable foreign regulatory authority. Although the FDA and other regulators impose requirements regarding our selection, qualification, oversight, and monitoring of our contract manufacturers and hold us responsible for the ultimate compliance of our products, we do not directly control the manufacturing process of our third- party contract manufacturers and are subject to risks associated with their ability to comply with cGMPs in connection with the manufacture of our products and product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others and the compliance concerns cannot be resolved, remediated, or otherwise addressed to the FDA' s or others' satisfaction in a timely manner during the review of

any marketing applications that we submit, it may negatively impact our ability to obtain regulatory approval for our drug candidates or obtain approval within projected timelines. We cannot guarantee the ability of our third- party manufacturers to maintain compliance with cGMP regulations, including having adequate quality control, quality assurance and qualified personnel. Further, our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products or product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our products or product candidates. Our reliance on third- party manufacturers entails additional risks, including: ● reliance on the third party for regulatory compliance and quality assurance; ● the possible breach of the manufacturing, supply or quality agreement by the third party; ● the possible misappropriation of our proprietary information, including our trade secrets and know- how; and ● the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. Moreover, our current long- term supply agreement for BRIUMVI contains certain minimum purchases in what are commonly referred to as a " take or pay " provision, and it is possible that future supply agreements could contain such provisions. To the extent our demand does not meet the minimum supply required amounts, we would be forced to pay more than desired. This could create a situation where we are spending more than required and could impact our ~~on- going~~ **ongoing** operations and entail curtailing other important research and development or commercialization efforts, all of which could have a material adverse effect on the Company. In negotiating our supply agreement for BRIUMVI, there is no guarantee that we have foreseen all eventualities or that our third- party manufacturer will be able to accommodate unforeseen changes in business direction in a timely fashion or at all. Scheduling of manufacturing at our third- party manufacturer is governed by contractual terms that require us to make investments in inventory of materials, with limited shelf- life, in advance of regulatory approval and based on preliminary commercial forecasting, and such inventory may not be used if timelines and supply needs shift. Our drug candidates and any drugs that we may develop may compete with other drug candidates and approved drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any third- party manufacturer with which we contract will have other clients, and our relative importance as a customer may adversely impact contractual terms or the performance of services in a satisfactory manner or on a timely basis. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval or interrupt commercial distribution. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers causing additional costs and delays in identifying and qualifying any such replacement. If a new contract manufacturer is not successful in replicating the product or experiences delays, or if regulatory authorities impose unforeseen requirements with respect to product comparability from multiple manufacturing sources, we may experience delays in clinical development or an interruption in our commercial supply. No assurance can be given that any new manufacturer will be successful or that material manufactured by a new manufacturer will perform comparably to product manufactured by the previous manufacturer or that the relevant regulatory agencies will agree with our interpretation of comparability. Any significant delays or gaps in supply of commercial or clinical products may adversely affect our clinical development program, our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis, and our future profit margins. We also rely on other third parties to store and distribute drug supplies for our clinical trials and for commercial demand for BRIUMVI and expect to continue to do so for any other potential commercial products. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any future product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue. The third parties upon whom we rely for the supply of starting materials, intermediates, active pharmaceutical ingredient (API) / drug substance, drug product, and other materials used in our drug candidates are our sole source of supply, and the loss or disruption of any of these suppliers could significantly harm our business. The starting materials, intermediates, API / drug substance, and drug product used in many of our drug candidates are currently supplied to us from single- source suppliers. Our ability to successfully develop our drug candidates, supply our drug candidates for clinical trials and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain starting materials, intermediates, API / drug substance, and drug product for these drugs in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. It is expected that many of our manufacturing partners will be sole source suppliers from single site locations for the foreseeable future. Various raw materials, components, and testing services required for our product and product candidates may also be single sourced. We are not certain that our single- source suppliers will be able to supply sufficient quantities of their products or on the timelines necessary to meet our needs, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers, our relative importance as a customer to those suppliers, international political conflicts that may impact trade or the supply chain within a particular region, ~~public~~ **global** health **crises** ~~emergencies such as the COVID- 19 pandemic~~ or natural disasters that may cause those suppliers to stop work for a period of time or lead to a sudden increase in demand for selected materials resulting in short- term unavailability of such materials. If any of our suppliers ceases operations for any reason or is unable or unwilling to supply starting materials, intermediates, API / drug substance, and drug product in sufficient quantities or on the timelines necessary to meet our needs, it could significantly and adversely affect our business, the supply of our drug products and drug candidates and our financial condition. In addition, if our current or future supply of any of our products or product candidates should fail to meet specifications during its stability program there could be a voluntary or mandatory product recall if the product is approved and, even in the absence of a recall, there could be significant interruption of our supply of drug, which would adversely affect the clinical development and commercialization of the product. We continually evaluate our supply chains to identify potential risks and needs for additional manufacturers and other suppliers for the production of our products and product candidates. Establishing additional or replacement suppliers for the API / drug substance, drug product, and certain raw materials, if

required, may not be accomplished quickly, or at all, and may involve significant expense. If we are able to find a replacement supplier, we would need to evaluate and qualify such replacement supplier and its ability to meet quality and compliance standards. Any change in suppliers or the manufacturing process could require additional regulatory approval and result in operational delays. While we seek to maintain adequate inventory of materials necessary for the production of our products and product candidates, any supply interruption or delay, or our inability to identify alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our commercialization and development efforts, which could harm our business, results of operations, financial condition and prospects. Because we have in- licensed BRIUMVI and our product candidates from third parties, any dispute with or non- performance by our licensors will adversely affect our ability to develop and commercialize the applicable product or product candidate. Because we license BRIUMVI and our product candidates from third parties and we expect to continue to in- license additional product candidates, if there is any dispute between us and our licensor regarding our rights under a license agreement, our ability to develop and commercialize the applicable product or product candidate may be adversely affected. Disputes may arise with the third parties from whom we license our products and product candidates for a variety of reasons, including: ● the scope of rights granted under the license agreement and other interpretation- related issues; ● the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement; ● the sublicensing of patent and other rights under our collaborative development relationships and obligations associated with sublicensing; ● our diligence obligations under the license agreement and what activities satisfy those diligence obligations; ● the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and ● the priority of invention of patented technology. In addition, the agreements under which we currently license BRIUMVI and our product candidates from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations, or may conflict in such a way that puts us in breach of one or more agreements, which would make us susceptible to lengthy and expensive disputes with one or more of our licensing partners. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product or product candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. If conflicts arise between us and our future collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies. If conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators or strategic partners, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for any future product candidates. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm any future product development efforts. We are dependent upon our relationships with collaboration and commercialization partners to further develop, fund, manufacture and commercialize our drug products and our product candidates. If such relationships are unsuccessful, or if a collaboration or commercialization partner terminates its collaboration or commercialization agreement with us, it could negatively impact our ability to conduct our business and generate net product revenue. Failure by a collaboration or commercialization partner to perform its duties under its collaboration or commercialization agreement with us (e. g. financial reporting or internal control compliance) may negatively affect us. On July 28, 2023, we entered into a ~~commercialization~~ **Commercialization** ~~agreement~~ **Agreement** (the Commercialization Agreement) with Neuraxpharm Pharmaceuticals, S. L. (Neuraxpharm), pursuant to which Neuraxpharm has the right to commercialize BRIUMVI in certain markets outside of the U. S **. On February 26, 2024, BRIUMVI was first made available in the European market by Neuraxpharm in Germany and is now commercially available in several other countries in the European Union and the United Kingdom** . In addition to the Commercialization Agreement, we may enter into collaboration arrangements with other collaboration and commercialization partners. We are subject to a number of risks associated with our dependence on our relationships with our collaboration and commercialization partners, including: ● **decisions by** our collaboration and commercialization partners ~~may~~ **to** terminate their collaboration or commercialization agreements with us for reasons specified in the collaboration or commercialization agreements, including our breach; ● the need for us to identify and secure on commercially reasonable terms the services of third parties to perform key activities, including development and commercialization activities, currently performed by our collaboration or commercialization partners in the event that a collaboration or commercialization partner terminates its agreement with us; ● adverse decisions by a collaboration or commercialization partner regarding the amount and timing of resource expenditures for the commercialization, distribution, and sale of our drug products; ● failure by a collaboration or commercialization partner to perform its duties under its agreement with us (e. g., its failure to comply with regulatory requirements which may disrupt its performance of its obligations under the agreement with us); ● failure by a collaboration or commercialization partner to timely deliver accurate and complete financial information to us or to maintain adequate and effective internal control over its financial reporting may negatively affect our ability to meet our financial reporting obligations as required by the SEC; ● failure by a collaboration or commercialization partner to timely deliver accurate and complete medical or clinical information to us or to maintain adequate and effective internal control over its pharmacovigilance activities and reporting may negatively affect our ability to meet our reporting

obligations as required by the FDA and other regulatory bodies; ● collaboration or commercialization partners' and their affiliates' development and commercialization of products that compete directly or indirectly with our products or product candidates; ● decisions by a collaboration or commercialization partner to prioritize others of its current or future products more highly than our drug products or our product candidates when it performs its duties; ● possible disagreements with a collaboration or commercialization partner as to the timing, nature and extent of our development plans or distribution and sales and marketing plans; and ● the **fact that** financial returns to us, if any, under our collaboration agreement with Neuraxpharm depends in large part on the achievement of milestones and generation of product sales, and if Neuraxpharm fails to perform or satisfy its obligations under the collaboration agreements, the development and commercialization of our drug products could be delayed, hindered or may not occur, and our business and prospects could be materially and adversely affected. While the Commercialization Agreement contains provisions that allow for dispute resolution, arbitration, and / or termination of the agreement by the Company in the event of a breach by Neuraxpharm, there can be no assurance that the Company and Neuraxpharm will agree on a cure for such a breach, and in the event of termination, there can be no assurance that the Company would be appropriately compensated and / or recover any losses sustained. Due to these factors and other possible disagreements with our collaboration and commercialization partners, we may be delayed or prevented from further developing, manufacturing or commercializing our drug products or our product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive. If any collaboration or commercialization partner were to terminate our relationship with it unilaterally, we would need to undertake development, commercialization or distribution or sale activities for our drug products and product candidates solely at our own expense, and / or seek one or more other partners for some or all of these activities in the U. S. or worldwide. If we pursued these activities on our own, it would significantly increase our capital and infrastructure requirements, might limit the indications we are able to pursue for our drug products and our product candidates, and could prevent us from effectively commercializing our drug products and our product candidates. If we sought to find one or more other pharmaceutical company partners for some or all of these activities, we may not be successful in such efforts, or they may result in collaborations that have us expending greater funds and efforts than our relationships with our current collaboration and commercialization partners. We may seek to establish additional collaborations, and if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Our drug development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund **related** expenses. ~~For~~ **Therefore, for** some of our drug candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those drug candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the **proposed** collaborator' s resources and expertise, the terms and conditions of the proposed collaboration **with a third party** , and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the likelihood of approval by the FDA, EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us. We may be restricted under our collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on ~~acceptable~~ **favorable** terms **to us** , or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on ~~acceptable~~ **favorable** terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and **we may ultimately not be able to** generate revenue from their sales. Risks ~~Relating~~ **Related** to Our Intellectual Property Our success depends upon our ability to obtain and protect our intellectual property and proprietary technologies. If the scope of our patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired **. At the same time, if the scope of our patent protection is too broad, our competitors may challenge the validity and enforceability of our patents** . Our commercial success in part depends on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to any product we commercialize, including BRIUMVI, our product candidates, their formulations and uses and the methods we use to manufacture them, as well as successfully defending these patents against third- party challenges. We seek to protect our proprietary and intellectual property position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures. Because we in- license our products and product candidates, we also rely on our licensors to protect the patent and other intellectual property rights necessary for commercialization. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them in the market they are being used or developed. The degree

of patent protection we require to successfully commercialize our products and product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect any of our products. In addition, the laws of foreign countries may not protect our patent rights to the same extent as the patent laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our product or product candidates, including generic versions of such drugs. Currently, we have several granted patents in the United States and EU, among other countries, and several pending patent applications that have not yet been issued or have been issued in certain jurisdictions but not all jurisdictions in which such applications have been filed. There can be no guarantee that any pending patent applications, nor any patent applications filed in the future will be granted in any or all jurisdictions in which they were filed, or that all patent claims initially submitted for examination in such patent applications will be allowed in the patent that is eventually granted, if at all. The patent prosecution process is subject to numerous risks and uncertainties, and there can be no assurance of the scope of patent claims that will ultimately be allowed, if at all, and no assurance that we or our partners will be successful in protecting our product and product candidates by obtaining and defending patents. These risks and uncertainties include the following: ● the patent applications that we or our licensors file may not issue as patent; ● patents that may be issued or in- licensed may be challenged, invalidated, modified, revoked or circumvented, or otherwise may not provide any competitive advantage; ● as of March 16, 2013, the United States converted from a first- to- invent to a first- to- file system. If we do not win the filing race, we will not be entitled to inventive priority; ● our competitors, many of whom have substantially greater resources than we do, and many of whom have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to file new patent applications covering our products, or make, use, and / or sell our products either in the United States or in international markets; ● there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns, which could limit our ability to fully monetize our intellectual property rights; and ● countries other than the United States may have less restrictive patent laws than those of the United States, allowing foreign competitors to exploit such less restrictive patent laws to make, use, and / or sell competing products in their respective jurisdictions. If we are not able to obtain patents that protect our product and product candidates, it could have a material adverse effect on our financial condition and results of operations. In addition, the patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to some of the pending patent applications covering our drug candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the United States Patent and Trademark Office (USPTO) can be significantly narrowed by the time they issue, if at all. It is also possible that we will fail to identify any patentable aspects of our research and development output and methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time- consuming process of filing patent applications and prosecuting them, it is possible that our product (s) or process (es) originally covered by the scope of our patent applications may change or be modified throughout the patent prosecution process, leaving our product (s) or process (es) without patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, that cover technology licensed from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our licensors or we fail to appropriately prosecute and maintain patent protection or trade secret protection for one or more products or product candidates, our ability to develop and commercialize such drugs may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to our product and product candidates could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability, which would have a material adverse effect on our financial condition and results of operations. Furthermore, should we enter into other collaborations, including out- licensing, joint development projects, partnerships, or strategic alternatives, we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of patents licensed or developed under such collaborations. Therefore, such patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. The patent laws of foreign countries may not protect our patent rights to the same extent as the laws of the United States, and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States patent law does. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U. S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the United States have taken an increasingly dim view of the patent

eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in those licensed from a ~~thirdparty~~ **third party** . In addition, U. S. patent laws may change, which could prevent or limit us, our subsidiaries, or our licensors from filing patent applications or patent claims to protect products and / or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents. For example, on September 16, 2011, the Leahy- Smith America Invents Act was signed into law. The Leahy- Smith Act includes a number of significant changes to United States patent law. These include the transition from a first- to- invent system to a first- to- file system and changes to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a quicker and less expensive process for challenging issued patents. The patents or patent applications owned or filed by us, or by our licensors or other collaborators, may be affected by third- party pre- issuance submissions of prior art to the USPTO, or by opposition, derivation, reexamination, inter parties review, post- grant review or interference proceedings. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U. S. patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by patents and patent applications for our drug candidates is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or product candidates. The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the U. S. and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with enough rights to exclude others from commercializing products similar or identical to ours. Even if our patent applications issue as patents, and they are unchallenged, our issued patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or drugs in a non- infringing manner. For example, a third party may develop a competitive drug that provides benefits similar to one or more of our products or product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our products or product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our products or product candidates could be negatively affected, which would harm our business. In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we have entered into agreements with many of our employees, consultants and advisors and any other third parties who have access to our proprietary know- how, information or technology for the purpose of assigning or granting similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and drug candidates. Such challenges may also result in our inability to manufacture or commercialize our products and product candidates without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Patent protection and other intellectual property protection are crucial to the success of our business and prospects, and there is a substantial risk that such protections ~~will~~ **may** prove inadequate. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other ~~means~~ **methods** in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our drugs or procedures, we may not be able to stop a competitor from marketing drugs that are the same as or similar

to our products or product candidates, which would have a material adverse effect on our business. If we do not obtain patent term extensions under the Hatch- Waxman Act and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business may be materially harmed. Depending on the timing, duration, and specifics of any FDA regulatory approval for our drug candidates, one or more of our licensed U. S. patents or future U. S. patents that we may license or own may be eligible for limited patent term restoration under the Hatch- Waxman Act. The Hatch- Waxman Act ~~permit~~ **permits** a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond ~~14~~ **fourteen** years from the date of product approval by the FDA, and only one patent covering the approved product may be extended. The application for a patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of the patent protection afforded could be less than what we request. If we are unable to obtain patent term extension or any term of such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected. We may not be able to enforce our intellectual property rights throughout the world. Filing, prosecuting and defending patents on drug candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our resources and attention from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which typically are very expensive, time- consuming and disruptive to our day- to- day business operations. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging invalidity of our or certain of our subsidiaries' patents or that we infringe their patents; or provoke those parties to petition the USPTO to institute inter parties review against the asserted patents, which may lead to a finding that all or some of the claims of the asserted patents are invalid. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our pending patents at risk of being invalidated, held unenforceable, or interpreted narrowly. In patent litigation in the United States, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Patents may be unenforceable if someone connected with the prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong as in the United States. If we lose a foreign patent lawsuit, alleging our infringement of a competitor' s patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a material adverse effect on our business. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Furthermore, adverse results on United States patents may affect related patents in our global portfolio. The adverse result could also put related pending patent applications at risk of not issuing. Additionally, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect

on the price of our common stock. Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or pending patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. The costs of these proceedings could be substantial. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our respective licensors' patent rights are highly uncertain. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. If we or our partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business. Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and technology, including interference proceedings before the USPTO. Our competitors or other third parties may assert infringement claims against us, alleging that our drugs are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product or product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product or product candidates of which we are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we or our licensors were the first to file for patent protection of such inventions. We are aware of certain patents that may pose issues for our commercialization of our product and product candidates. If we decide to initiate proceedings to challenge the validity of these patents in the future, we may be unsuccessful, as courts or patent offices in the United States and abroad could uphold the validity of any such patents. If we were to challenge the validity of any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent' s claims. If we are unable to do so, we may be forced to delay the launch of our product candidates or launch at the risk of litigation for patent infringement, which may have a material adverse effect on our business and results of operations. If a third- party claims that we or any collaborators of ours infringe their intellectual property rights, we may have to defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our drug candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain such a license, it could be granted on non- exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or drug candidates. In addition, we could be found liable for monetary damages, including treble damages and attorney' s fees if we are found to have willfully infringed such third- party patent rights. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business. No assurance can be given that patents issued to third parties do not exist, have not been filed, or could not be filed or issued, which contain claims covering their products, technology or methods that may encompass all or a portion of our products and methods. Given the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a risk that third parties may allege they have patent rights encompassing our products or methods. Other products or product candidates that we may in- license or acquire could be subject to similar risks and uncertainties. We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties, whom may or may not be interested in granting such a license, on commercially reasonable terms, in which case our business could be harmed, possibly materially. For example, we engage extensively with third parties, including academic institutions, to conduct non- clinical and clinical research on our product and product candidates. While we seek to ensure all material transfer

and service agreements governing this research provide us with favorable terms covering newly generated intellectual property, a general principle under which much of this research with academic institutions is conducted provides third- party ownership of newly generated intellectual property, with an exclusive option available for us to obtain a license to such intellectual property. Through the conduct of this research, it is possible that valuable intellectual property could be developed by a third party, which we will then need to license in order to better develop or commercialize our products. No assurance can be given that we will be able to successfully negotiate such a license on commercially reasonable terms, or at all. Further, should we fail to successfully negotiate a license to such intellectual property, most institutions are then free to license such intellectual property to any other third party, including potentially direct competitors of ours. Should we fail to adequately secure a license to any newly generated intellectual property, our ability to successfully develop or commercialize our products may be hindered, possibly materially. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed. In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know- how and continuing technological innovation to develop and maintain our competitive position. With respect to the building of our proprietary compound library, we consider trade secrets and know- how to be our primary intellectual property. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our consultants and employees. We may not be able to prevent the unauthorized disclosure or use of our technical know- how or other trade secrets by the parties to these agreements, however, despite the existence of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees and consultants who are parties to these agreements breach or violate the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time- consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Our trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our drug candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' drugs, our competitive position could be adversely affected, as could our business. We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our drug candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates, which would have an adverse effect on our business, results of operations and financial condition. Risks Related to Our Business Organization and Governance, Strategy, Employees and Growth Management If we fail to attract and keep key management, commercial, and clinical development personnel, we may be unable to successfully develop or commercialize our product and product candidates. We are highly dependent on the research and development, commercialization, manufacturing, quality, financial and legal expertise of our senior management team as well as the other principal members of our management. Although we have entered into an employment agreement with our chief executive officer and employment letters with our senior managers, each of our executive officers may terminate their employment with us at any time. We do not maintain key person insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. Recruiting and retaining qualified scientific, clinical, manufacturing and medical affairs, and commercial personnel, particularly in MS, will be critical to our success. The loss of the services of our chief executive officer or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition

to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercialization objectives, our ability to raise additional capital, and our ability to implement our business strategy. We will need to develop and expand our business, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations. We may attempt to expand our business by acquiring additional businesses or drugs, forming strategic alliances or creating joint ventures with third parties. We may encounter numerous difficulties in developing, manufacturing, and marketing any new products resulting from any such arrangement or transaction that may delay or prevent us from realizing their expected benefits. If we are unable to successfully integrate such acquired businesses with our existing operations and company culture, we may never realize the benefits of such acquisitions or strategic alliances. We cannot assure you that, following any such transaction, we will achieve the expected synergies to justify the transaction. As of February ~~26~~ **25** , ~~2024~~ **2025** , we had **338** ~~264 full- time~~ employees. To manage our anticipated future growth and focus in **the** ~~neurology~~ **neurological** and ~~immunology~~ **immunological fields** , we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day- to- day activities and devote a substantial amount of time to managing these activities. Due to our limited resources, we may not be able to effectively manage the expansion and shift of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage our transition to a strategy primarily focused on **the** ~~neurology~~ **neurological** and ~~immunology~~ **immunological fields** , our expenses may increase more than expected our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and changes to our business. Additionally, to help manage the evolving needs, we may utilize the services of outside vendors or consultants to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development, chemistry, manufacturing, controls, and other pharmaceutical development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on a substantial number of consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors when needed, we may be unable to successfully implement the tasks necessary to achieve our research, development and commercialization goals. Certain anti- takeover provisions in our governing documents and Delaware law could make a third- party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock. Certain provisions in our amended and restated certificate of incorporation and restated bylaws may make it more difficult for a third party to acquire us or discourage a third party from attempting to acquire or control us and may limit the price that certain investors might be willing to pay in the future for shares of our common stock. For example, our amended and restated certificate of incorporation allows us to issue preferred stock without the approval of our stockholders, the issuance of which could decrease the amount of earnings and assets available for distribution to, or affect the rights and powers, including voting rights, of our common stockholders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. In addition, our restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control. ~~On July 18, 2014, the Board of Directors declared a distribution of one right for each outstanding share of common stock. The rights may have certain anti- takeover effects. The rights will cause substantial dilution to a person or group that attempts to acquire us on terms not approved by the Board of Directors unless the offer is conditioned on a substantial number of rights being acquired. However, the rights should not interfere with any merger, statutory share exchange or other business combination approved by the Board of Directors since the rights may be terminated by us upon resolution of the Board of Directors. Thus, the rights are intended to encourage persons who may seek to acquire control of the Company to initiate such an acquisition through negotiations with the Board of Directors. However, the effect of the rights may be to discourage a third party from making a partial tender offer or otherwise attempting to obtain a substantial equity position in the equity securities of, or seeking to obtain control of, the Company. To the extent any potential acquirers are deterred by the rights, the rights may have the effect of preserving incumbent management in office.~~ Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50 % change (by value) in the ownership of its equity over a three- year period), the corporation' s ability to use its pre- change net operating loss carryforwards and certain other pre- change tax attributes to offset its post- change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As **a result** ~~of December 31~~ , **if** ~~2023,~~ we ~~had federal~~ **earn net taxable income, our ability to use our pre- change** net operating loss carryforwards ~~of approximately $ 1. 4 billion, and our ability~~ to ~~utilize those~~ **offset our taxable income may be**

subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. Accordingly, even if we attain profitability, we may be unable to use a material portion of our net operating loss carryforwards ~~could be limited by an~~ **and other tax attributes** ~~ownership change as described above~~ , which could **adversely affect** ~~result in increased tax liability to us. In addition, pursuant to the Tax Act, we may not use net operating loss carry- forwards to reduce~~ our **future cash flows** ~~taxable income in any year by more than 80 %, and we may not carry back any net operating losses to prior years. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed by President Trump. Certain provisions of the CARES Act alter the rules regarding net- operating losses for such losses arising in 2018, 2019 and 2020. Such losses may be carried back for five years. We cannot assure you, however, of our ability to utilize these favorable offset rules within the applicable time period. These rules apply regardless of the occurrence of an ownership change~~ . Certain of our executive officers, directors, principal stockholders and their affiliates maintain the ability to exercise significant influence over our company and all matters submitted to stockholders for approval. Certain of our executive officers, directors and stockholders own more than 5 % of our outstanding common stock and, together with their affiliates and related persons, beneficially own a significant percentage of our capital stock. If these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. In addition, this concentration of ownership might adversely affect the market price of our common stock by: ● delaying, deferring or preventing a change of control of us; ● impeding a merger, consolidation, takeover or other business combination involving us; or ● discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. Our internal information technology systems, or those of our third- party CROs, CMOs, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug candidates' development programs and our commercialization of any products for which we receive regulatory approval. Despite the implementation of security measures, our internal information technology systems and those of our third- party CROs, CMOs, and other contractors and consultants are vulnerable to damage from ~~computer viruses,~~ unauthorized access, **security breach** ~~cyber- attacks~~ or **incidents** ~~cyber- intrusions over the Internet~~ , natural disasters, terrorism, war and telecommunication and electrical failures. **Security breaches include, but are not limited to, deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our and our third- party service providers' systems and the information on such systems. Security breaches can also include phishing attempts or e- mail fraud to cause unauthorized payments or information to be transmitted to an unintended recipient, or to permit unauthorized access to systems.** Although we have ~~been~~ **experienced security breaches in** the **past** ~~targets of cyber- attacks and cyber- intrusions~~ , the impact on our operations and financial condition has not been material. We expect such cybersecurity threats to continue and become more sophisticated **. Threat actors** , ~~even more so due to~~ **including nation state attackers, could also use artificial intelligence for malicious purposes, increasing the frequency and complexity of** ~~the~~ **their attacks** ~~conflict between Russia and Ukraine~~ . A significant **security breach** ~~cyber- attack~~ or **incident** ~~cyber- intrusion~~ could cause our systems to fail, **compromise** ~~leakage of~~ confidential information, or **cause significant** business ~~interruption~~ **interruptions** , which could result in a material disruption of our operations, financial loss, or reputational harm. For example, the loss of clinical trial data for our drug candidates could result in delays in our regulatory approval efforts **, violate healthcare privacy laws and regulations** and significantly increase ~~our~~ **the** ~~costs~~ **cost of remediation** ~~to recover or reproduce the data~~ . We have invested in protections and monitoring practices of our data and information technology systems to reduce these risks and expect to continue do so as our information technology systems increase in magnitude and complexity. However, there can be no assurance that our efforts and investments will prevent breakdowns or breaches in our systems that could adversely affect our business. Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Key national economies, including the United States, have been affected from time to time by economic downturns or recessions, supply chain constraints, ~~rising~~ **high** inflation, restricted credit, poor liquidity, reduced corporate profitability, debt, equity and foreign exchange market volatility, bankruptcies, ~~rising~~ **high** interest rates, **high** unemployment rates and overall uncertainty with respect to the economy. ~~Increasing~~ **In particular, fluctuating and / or high** interest rates in the United States to respond to inflationary pressures and market volatility **may** ~~, as well as the government closures of Silicon Valley Bank and Signature Bank and liquidity concerns at other financial institutions, could negatively impact our results~~ **result in** ~~of operations and financial condition. In addition, increased interest rates or~~ a general economic downturn or recession **, which** could reduce our ability to raise additional capital when needed on acceptable terms, if at all ~~. A weak~~ **, and negatively impact** ~~or~~ **our** ~~declining economy, supply disruptions or international trade disputes could also strain our third- party suppliers, possibly resulting~~ **results** ~~in supply disruption~~ **of operations and financial condition** . Likewise, the capital and credit markets may be adversely affected by ~~the~~ **geopolitical** conflicts ~~between Russia~~ and ~~Ukraine and Israel and Hamas, the possibility of wider European, Middle Eastern or global conflicts, and the~~ global sanctions imposed in response thereto. Other international events such as trade disputes, ~~separatist movements~~ **increased tariffs or retaliatory tariffs** , leadership changes and political and military conflicts could also adversely affect global financial activity and markets and could negatively affect the U. S. economy. These conditions could result in decreased economic activity, heightened risk of cyberattacks and inflation, as well as impact our ability to raise capital. Additionally, the Federal Reserve Board (FRB) and other major central banks have been consistently removing or reducing monetary accommodation, increasing the risk of recession and also potentially negatively impacting asset values and credit spreads that were boosted by extraordinary monetary stimulus. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our drug candidates and our ability to raise additional capital

when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our marketed product and services. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions, could adversely impact our business. Our employees, principal investigators, CROs, CMOs and consultants may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business. We are exposed to the risk that our employees, principal investigators, CROs, CMOs, and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our ~~pre- clinical~~ **preclinical** studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of ethics applicable to all of our employees and have implemented a compliance program, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. In addition, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, regardless of the outcome, our reputation and our business may suffer. If we are not successful in defending ourselves or asserting our rights, those actions could lead to imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business. We may acquire businesses or drugs, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions. We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders, tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. ~~On December 22~~ **Following the change in U. S. administration** , ~~2017, legislation commonly referred to as the~~ **there** ~~Tax Act was signed into law and~~ is **uncertainty regarding future U** ~~generally effective after December 31, 2017~~ . ~~The Tax Act makes significant~~ **S. policies and legislative and regulatory** changes **related** to **taxation and importation, which could adversely impact** the ~~United States federal income~~ **global economy and our operating results. To the extent that future U. S.** tax **policy** ~~rules for taxation of individuals and business entities. Most of the~~ changes **have** ~~applicable to individuals are temporary and apply only to taxable years beginning after December 31, 2017 and before January 1, 2026. For corporations, the Tax Act reduces the top corporate income tax rate to 21 % and repeals the corporate alternative minimum tax, limits the deduction for net interest expense, limits the deduction for net operating losses and eliminates net operating loss carrybacks, modifies or repeals many business deductions and credits, shifts the United States toward~~ a **negative** ~~more territorial tax system, and imposes new taxes to combat erosion of the U. S. federal income tax base. The Tax Act makes numerous other large and small changes to the federal income tax rules that may affect potential investors and may directly or indirectly affect us. We continue to examine the~~ impact ~~this tax reform legislation may have on our business. However, the effect of the Tax Act~~ on us, ~~whether adverse or favorable, is~~ **including as a result of related** ~~uncertain~~ **uncertainty** , **these changes could adversely impact** ~~and may not become evident for some period of time. This document does not discuss such legislation or~~ **our business** ~~the manner in which it might affect us or purchasers of our common stock. Prospective investors are urged to consult with their legal and tax advisors with respect to the Tax Act and any other regulatory or administrative developments and proposals~~ , **results of operations** and **financial position** ~~their potential effects on them based on their unique circumstances~~ . ~~General Risks~~ Risks Related to Our Common Stock and Being a Publicly Traded Company Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell **our** stock at a profit. The trading price of our common stock has been and is likely to continue to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include, among others: ● reception and success of BRIUMVI in the U. S. market; ● **reception and success of BRIUMVI in the German market and** the anticipated launch of BRIUMVI in **additional** European markets; ● publicity regarding actual or potential clinical results relating to our product or products under development by our competitors or us; ● delay or failure in initiating, completing or analyzing nonclinical or

clinical trials or the unsatisfactory design or results of these trials; ● achievement or rejection of regulatory approvals by us or our competitors; ● any delay in our regulatory review for products and product candidates we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation a change to the projected approval date, scheduling of an advisory committee meeting or issuance of a " refusal to file " letter; ● announcements of technological innovations or new commercial products by our competitors or us; ● developments concerning proprietary rights, including patents; ● developments concerning our collaborations; ● **announcements of technological innovations by us or our competitors; ● actual or anticipated variations in our operating results due to the level of development expenses and other factors; ● conditions and trends in the pharmaceutical, biotechnology and other industries; ●** regulatory developments in the United States and foreign countries; ● **litigation or arbitration; ●** economic **, political and market conditions** or other crises and other external factors such as the disruptions in the global economy caused by **global health crises and geopolitical** ~~the COVID- 19 pandemic, the conflict~~ **conflicts** ~~between~~ **in** Russia and Ukraine ~~,~~ and the **Middle East** ~~Israel- Hamas war~~ ; ● period- to- period fluctuations in our revenues and other results of operations; ● failure to meet our revenue projections or guidance; ● changes in financial estimates by securities analysts; ~~and~~ **● our repurchase of shares of our common stock pursuant to our share repurchase program; ●** sales of our common stock by us **; and ● the occurrences of any of the other risks described in this Annual Report on Form 10- K** . We will not be able to control many of these factors, and we believe that period- to- period comparisons of our financial results will not necessarily be indicative of our future performance. In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. We are subject to risks related to corporate social responsibility and reputational matters. Our reputation and the reputation of our brands, including the perception held by our customers, end- users, business partners, investors, other key stakeholders and the communities in which we do business are influenced by various factors. There is an increased focus from our stakeholders on Environmental, Social, and Governance (ESG) practices and disclosure- and if we fail, or are perceived to have failed, in any number of ESG matters, such as environmental stewardship, inclusion and diversity, workplace conduct and support for local communities, or if we fail, or are perceived to have failed, to effectively respond to changes in legal or regulatory requirements concerning climate change or other sustainability concerns, our reputation or the reputation of our brands may suffer. Such damage to our reputation and the reputation of our brands may negatively impact our business, financial condition and results of operations. In addition, negative or inaccurate postings or comments on social media or networking websites about the Company or our brands could generate adverse publicity that could damage our reputation or the reputation of our brands. If we are unable to effectively manage real or perceived issues, including concerns about product quality, safety, corporate social responsibility or other matters, sentiments toward the Company or our products could be negatively impacted, and our financial results could suffer. **Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, supply chain, results of operations, financial condition and growth prospects. We believe that climate change has the potential to negatively affect our business, results of operations, financial condition and growth prospects. The adverse impacts of climate change include (i) physical risks such as increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat, (ii) risks in transitioning to a low- carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and (iii) social and human effects (such as population dislocations and harm to health and well- being). Since we currently rely on single contract manufacturers to produce our commercial products, extreme weather and sea level rise pose physical risks to the facilities of our manufacturing partners. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and operational disruptions** ~~Because~~ **-- caused by such natural disasters and extreme weather events. Loss of access to the facilities of our manufacturing partners may result in increased costs, delays in the development of our products or interruption of our business operations. Any disaster recovery and business continuity plans that our** we ~~do not anticipate paying~~ **or our third- party manufacturers have in place may prove inadequate in the event of a serious natural disaster or similar event. We may incur substantial expenses as a result of the limited nature of these disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long- term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear and may heighten or intensify the existing risk of natural disasters. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, we cannot assure you that such insurance coverage will be sufficient to satisfy** any ~~cash~~ **damages and losses we may directly or indirectly incur. If the manufacturing facilities of our third- party manufacturers are unable to operate for any reason, even for a short period of time, any or all of our research and development programs or commercialization efforts may be harmed. Any material interruption could have a material and adverse effect on our business. New legal or regulatory requirements may also be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in our manufacturing partners being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrading of facilities to meet new building codes, and the redesign of utility systems, which could increase our third- party manufacturers' operating costs, including the cost of electricity and energy used to develop our products. Our supply chain as a whole would likely be subject to these same transitional risks and would likely pass along any increased costs to us. Our ability to pay** dividends ~~on our capital stock in the foreseeable~~

~~future, capital appreciation~~ , if any, **are limited, and** ~~will likely be the sole source of gain for~~ our stockholders **may not receive any return** ~~. We have never declared or paid cash dividends~~ on ~~our capital~~ **investment unless they sell their common** stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. However, any future determination relating to the use of our future earnings, **including the declaration, amount and payment of any future dividends on shares of our common stock,** if any, will be made at the discretion of the Board of Directors and will depend on a number of factors, including capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that the Board of Directors may deem relevant. In addition, under the **Financing** ~~Amended Loan~~ Agreement ~~, as amended, with Hercules~~ , we are currently restricted from paying cash dividends, and we expect these restrictions to continue in the future. Furthermore, the terms of any future debt agreements may continue to preclude us from paying dividends. As a result, ~~capital appreciation, if~~ **our stockholders may not receive** any ~~, of our~~ **return on investment unless they sell their** common stock ~~will be likely the sole source of gain for our stockholders for the foreseeable future~~ . An active trading market for our common stock may not be sustained, and investors may not be able to resell their shares at or above the price they paid. Although we have listed our common stock on the Nasdaq Capital Market, an active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the price at which they acquired their shares or at the time that they would like to sell. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. If equity research analysts do not publish research or reports about our business or if they publish negative evaluations of or downgrade our common stock, the price of our common stock could decline. The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. If one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause our common stock price to decline. We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. As a public company, we incur significant legal, accounting and other expenses under the Sarbanes- Oxley Act of 2002, as well as rules subsequently implemented by the SEC, and the rules of any stock exchange on which we are listed. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our team has devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. The Sarbanes- Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes- Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal control over financial reporting. These efforts to comply with Section 404 will require the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal control over financial reporting and all other aspects of Section 404, we cannot be certain that **material weaknesses will not be identified when we test the effectiveness of our control systems. For example, we identified** a material weakness **in** ~~will not be identified when we test the effectiveness of~~ our **internal** control ~~systems in~~ **over financial reporting during** the ~~future~~ **fiscal quarter ended June 30, 2024, which has been remediated as of December 31, 2024 (as discussed below)** . If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal control over financial reporting, which could have an adverse effect on the market price of our stock **and result in a loss of investor confidence in our financial reports. We identified a material weakness in our internal control over financial reporting related to non- routine share- based payment awards, which has been remediated. If we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired. During the preparation of our unaudited condensed consolidated financial statements for the period ended June 30, 2024, we identified a material weakness in our internal control over financial reporting related to a process- level control over share- based payment awards not being designed effectively. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. To remediate the material weakness, the Company has designed and implemented additional preventative controls around non- routine share- based payment awards to ensure the appropriate recognition and measurement of such awards, and enhanced risk assessment procedures to ensure that all non- routine share- based payment awards are appropriately identified and evaluated. Management, including our Chief Executive Officer and Chief Financial Officer, has performed testing to verify the effective design and successful operating effectiveness of the new or enhanced controls, determined that control activities have operated effectively for a sufficient period of time and concluded that the previously disclosed material weakness has been remediated as of December 31, 2024. We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. If we**

are unable to further implement and maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods could be adversely affected, which could subject us to litigation or investigations requiring management resources and payment of legal and other expenses, negatively affect investor confidence in our financial statements and adversely impact our stock price. In addition, any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. If we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected and we could become subject to litigation or investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources . Volatility in the price of our common stock may subject us to securities and shareholder derivative litigation, which could cause us to incur substantial costs and divert management' s attention, financial resources and other company assets. In the past, securities class action and shareholder derivative litigation has often been brought against a company following periods of volatility in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. Past lawsuits and any future lawsuits to which we may become a party are subject to inherent uncertainties and will likely be expensive and time- consuming to investigate, defend, and resolve, and will divert our management' s attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and other suits in which we may not prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of substantial monetary damages or fines, or we may decide to settle this or other lawsuits on similarly unfavorable terms, which could adversely affect our business, financial condition, results of operations or stock price. Future sales of our common stock, including by us or our directors and executive officers or shares issued upon the exercise of currently outstanding options, could cause our stock price to decline. A substantial portion of our outstanding common stock can be traded without restriction at any time. In addition, a portion of our outstanding common stock is currently restricted as a result of federal securities laws but can be sold at any time subject to applicable volume limitations. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, by us or others, could reduce the market price of our common stock or impair our ability to raise adequate capital through the sale of additional equity securities. In addition, we have a significant number of shares that are subject to outstanding options. The exercise of these options and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We cannot predict the number, timing or size of future issuances or the effect, if any, that any future issuances may have on the market price for our common stock. **We cannot guarantee that our stock repurchase program will be further consummated or will enhance stockholder value, our share repurchase program could affect the price of our common stock and increase volatility and may be suspended or terminated at any time, which may result in a decrease in the trading price of our common stock. In August 2024, we announced that our Board of Directors had authorized a share repurchase program of up to $ 100 million of our outstanding shares of common stock. We intend to repurchase shares of our common stock from time to time, as authorized by our Board of Directors, through open market purchases, in privately negotiated transactions or by other means, including through the use of trading plans intended to qualify under Rule 10b5- 1 under the Exchange Act, in accordance with applicable securities laws and other restrictions. The timing and the amount of stock repurchases in the share repurchase program will be determined by our management, based on its evaluation of factors including business and market conditions, corporate and regulatory requirements, and other considerations. The share repurchase program does not have a fixed expiration date, may be suspended or discontinued at any time, and does not obligate us to acquire any amount of our common stock. For more information about our share repurchase activities for the year ended December 31, 2024, see the section entitled " Purchases of Equity Securities by the Issuer and Affiliated Purchasers " in Part II, Item 5. There can be no assurance of any future share repurchases or share repurchase program authorizations. The timing and manner of any share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, results of operations and financial condition, alternative investment opportunities, restrictions under any of our agreements, business economic and market conditions, corporate and regulatory requirements the price of our Common Stock on the NASDAQ Capital Market, and other factors that we may deem relevant. We can provide no assurance that we will repurchase shares of our Common Stock at favorable prices, if at all. Repurchases pursuant to our share repurchase program could affect our stock price and increase its volatility or diminish our cash reserves, which may impact our ability to finance our future operations. The existence of a share repurchase program could also cause our stock price to be higher than it would be in the absence of such a program and could potentially reduce the market liquidity for our common stock. There can be no assurance that any repurchases will enhance shareholder value, because the market price of our common stock may decline below the levels at which we repurchased our common stock. Although our share repurchase program is intended to enhance long- term shareholder value, short- term stock price fluctuations could reduce the share repurchase program' s effectiveness.**