Risk Factors Comparison 2025-03-24 to 2024-03-27 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully read and consider all of the risks described below, as well as the other information in this Annual Report on Form 10- K, including our **consolidated** financial statements and related notes thereto and the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations ". The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations and future prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock. Risks Related to Our Financial Position, and Additional Capital Needs We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. Our net losses were $ **86. 9 million and $** 76. 4 ~~million and $ 58. 8~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~287~~ **374** . ~~3~~ **2** million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to increase significantly as we continue clinical development for bel- sar and continue to discover and develop additional product candidates. In addition, if we obtain regulatory approval for our product candidates, we will incur significant sales, marketing and manufacturing expenses. We **incur costs, and** will incur additional costs **,** associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all ~~. We have no products approved for commercial sale and, therefore, have never generated any revenue from product sales, and we do not expect to in the foreseeable future. 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 revenue~~ . To date, we have not generated any revenue from any product sales. **Our ability to become profitable depends upon our ability to generate revenue.** We have no products approved for commercial sale ~~,~~ and **, therefore, have never generated any revenue from product sales, and we do not expect to in the foreseeable future. Further, we** do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including: ▪ initiating and completing research regarding, and preclinical and clinical development of, bel- sar in primary choroidal melanoma and ~~,~~ additional oncology indications, including ~~NMIBC,~~ **metastases to the choroid and bladder cancer as well as any** other research programs from our VDC technology platform and any future product candidates; ▪ obtaining marketing approval for bel- sar and any future product candidates for which we complete clinical trials; ▪ transferring our manufacturing process to **, and developing and maintaining it with,** a CDMO for bel- sar and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties; ▪ launching and commercializing bel- sar and any future product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor; ▪ obtaining market acceptance of bel- sar and any future product candidates as viable treatment options; ▪ addressing any competing technological and market developments; ▪ identifying, assessing, acquiring and developing new product candidates from our VDC technology platform; ▪ negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; ▪ obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know- how; and ▪ attracting, hiring, and retaining qualified personnel. Even if bel- sar or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market bel- sar or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for bel- sar and any future product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our

operations. A decline in the value of our company could also cause you to lose all or part of your investment. We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or terminate one or more of our research and development programs, future commercialization efforts, product development or other operations. Since our inception, we have used substantial amounts of cash to fund our operations, and our expenses will increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate and complete clinical trials of, and seek marketing approval for bel- sar. Identifying and developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time- consuming, expensive and uncertain process that takes years to complete. Even if one or more of bel- sar or any future product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA , or other regulatory agencies to perform clinical trials or nonclinical studies in addition to those that we are currently conducting or anticipate. Other unanticipated costs may also arise. Because the design and outcome of our current and planned clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of bel- sar or any future product candidates that we develop. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations. Based on our current operating plan, we believe that our existing cash and cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditures into the second half of 2026. Advancing the development of bel- sar and other research programs will require a significant amount of capital. Our existing cash and cash equivalents will not be sufficient to fund bel- sar through regulatory approval, and we anticipate needing to raise additional capital to complete the development and commercialization of bel- sar. Our estimate as to how long we expect our existing cash and cash equivalents to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. We will be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize product candidates. Disruptions in financial markets due to unfavorable global economic conditions and inflationary pressures may make equity and debt financings more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. To the extent that we raise additional capital through the sale of equity or convertible preferred stock, each investor' s ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect each investor' s rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to commercialize bel- sar if and when approved and develop our product candidates. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our clinical trials, research and development programs, future commercialization efforts or other operations. Recent volatility in capital markets may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness. Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new solutions, retain or expand our current levels of personnel, improve our existing solutions, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to: ▪ finance unanticipated working capital requirements; ▪ develop or enhance our technological infrastructure and our existing solutions; ▪ pursue acquisitions or other strategic relationships; and ▪ respond to competitive pressures. Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital- raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our businesses. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights to our technologies or product candidates. We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings,

collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, existing stockholder ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek commercial or development partners for our lead products or any future product candidate at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development, regulatory approval and commercialization of our product candidates. We rely on our team' s expertise in drug discovery, translational research and patient- driven precision medicine to develop our product candidates. Our business depends significantly on the success of this engine and the development and commercialization of the product candidates that we discover with this engine. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales in the near term, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives, including: ▪ successful and timely completion of preclinical and clinical development of bel- sar in **small choroidal melanoma and** indeterminate lesions ~~and primary choroidal melanoma~~ and additional oncology indications, including but not limited to **metastases to the choroid and** bladder cancer, other research programs from our VDC technology platform, and any other future programs; ▪ establishing and maintaining relationships with CROs and clinical sites for the clinical development of bel- sar, other research programs from our VDC technology platform, and any other future programs; ▪ timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development; ▪ transferring our manufacturing process to **, and developing or maintaining it with,** a CDMO including obtaining finished products that are appropriately packaged for sale; ▪ establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services ~~,~~to support clinical development and meet the market demand for our product candidates, if approved; ▪ successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in- house or with one or more collaborators; ▪ a continued acceptable safety profile following any marketing approval of our product candidates; ▪ commercial acceptance of our product candidates by patients, the medical community and third- party payors; ▪ satisfying any required post- marketing approval commitments to applicable regulatory authorities; ▪ identifying, assessing and developing new product candidates from our VDC technology platform; ▪ obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally; ▪ defending against third- party interference or infringement claims, if any; ▪ entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates; ▪ obtaining coverage and adequate reimbursement by third- party payors for our product candidates; ▪ addressing any competing therapies and technological and market developments; and ▪ attracting, hiring and retaining qualified personnel. We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations. Risks Related to the Discovery and Development of our Product Candidates We are heavily dependent on the success of bel- sar, our only product candidate to date. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to development of bel- sar in multiple oncology indications, which is currently our only product candidate. Accordingly, our business currently depends heavily on the successful development, regulatory approval, and commercialization of bel- sar. We can provide no assurance that bel- sar will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of bel- sar or if bel- sar does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever. The research, testing, manufacturing, safety, efficacy, recordkeeping, labeling, approval, licensure, sale, marketing, advertising, promotion and distribution of bel- sar is, and will remain, subject to comprehensive regulation by the FDA and foreign regulatory authorities. Failure to obtain regulatory approval for bel- sar in the United States, Europe and other major markets around the world will prevent us from commercializing and marketing bel- sar in such jurisdictions. Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for bel- sar, any approval might contain significant limitations related to use, including limitations on the stage or type of cancer bel- sar is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications, or requirement for a **risk evaluation and mitigation strategy, or** REMS. Any such limitations or restrictions could similarly impact any supplemental marketing approvals we may obtain for bel- sar. Furthermore, even if we obtain regulatory approval for bel- sar, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third- party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize bel- sar, we may not be able to generate sufficient revenue to

continue our business. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for bel- sar, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired. Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We utilize third- party CROs and / or regulatory consultants to assist us in the regulatory approval process globally and expect to continue to do so in the future. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate' s safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities and clinical sites by the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, Premarket Approval, or PMA, or **biologics license application, or** BLA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Because the activity of bel- sar in ocular melanoma requires a drug delivery device and activation by a laser, the regulatory complexity of the product candidate is greater than for products that ~~don-~~ **do not** ~~' t~~ utilize a device, which creates uncertainties in the requirements for regulatory approval. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following: ▪ the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; ▪ we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; ▪ the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ▪ we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ▪ the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; ▪ the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an BLA or other submission or to obtain regulatory approval in the United States or elsewhere; ▪ the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or those of third- party manufacturers with which we contract for clinical and commercial supplies; and ▪ the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process, as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. Our novel VDC product candidates are based on a technology that we are in the process of developing. We expect the novel nature of such product candidates to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials. Additionally, the conduct of Advisory Committee meetings may be disrupted or delayed and the impact that may have on the overall timing of regulatory approvals is uncertain. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. We have initiated but not yet completed a pivotal clinical trial nor have we commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects. We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, the EMA, or other regulatory agencies to market bel- sar or any future product candidate. Carrying out later- stage clinical trials is a complicated process. Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research and Phase 1 and Phase 2 clinical trials for our product candidates, primarily related to our bel- sar program in **small choroidal melanoma and** indeterminate lesions ~~and primary choroidal melanoma~~ . ~~We have not yet demonstrated an ability to successfully complete pivotal clinical trials, though~~ **Although** we have an ongoing global Phase 3 trial in small choroidal melanomas and indeterminate lesions, **we have not yet demonstrated an ability to successfully**

complete pivotal clinical trials, obtain marketing approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. In order to complete later stage or pivotal trials, we are expanding our clinical operations, CMC and regulatory capabilities, and we may be unable to recruit and train qualified personnel or sign a contract with a global clinical research organization to conduct ~~the~~ **such** trials on our behalf. Consequently, we may be unable to successfully and efficiently design, execute and complete necessary clinical trials in a way that leads to approval of bel- sar or future product candidates. We may require more time to enroll patients and incur greater costs than our competitors and may not succeed in obtaining global regulatory approvals of product candidates that we develop. Furthermore, we may conduct **a** ~~our first~~ pivotal trial based on an adaptive design, which could increase the time spent on or costs associated with this trial. We **have** ~~are in the process of transferring~~ **transferred** our ~~intended commercial~~ manufacturing process to our intended external CDMO commercial ~~manufacturing~~ **manufacturer , but** ~~site. During this transfer~~ **transfers** ~~process~~ **to additional CDMOs may occur in the future. Further** , some modifications **to our manufacturing process** may be needed to ensure manufacturability and ability to scale- up the process to commercial batch sizes **and to meet worldwide regulatory standards for commercial manufacture** . We intend to perform an analytical comparability assessment between the current clinical process and the intended commercial process, however, if this analytical process comparability assessment is unsuccessful, clinical comparability **or other studies** may be required, which may result in delayed regulatory approval. We do not anticipate a change in formulation. However, failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by clinical-stage biopharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. If we fail to develop additional product candidates, or obtain additional indications of our first product candidate, our commercial opportunity could be limited. We expect to focus our resources on the development of bel- sar in the near term. Developing, obtaining marketing approval for, and commercializing any future product candidates will require substantial additional funding and will be subject to the risks of failure inherent in drug product development. We cannot assure you that we will be able to successfully advance any future product candidates through the development process. Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market any future product candidates for any indication, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed. Bel- sar is a biologic that requires the use of multiple medical devices, which may result in additional regulatory risks. Bel- sar is a novel biologic for which the intended use in ocular oncology requires delivery to the **suprachoroidal space, or** SCS **,** and activation by a laser. For ocular oncology indications, we use Clearside **Biomedical Inc.** ' s SCS Microinjector ®, or the SCS Microinjector, to deliver bel- sar into the SCS. In the United States, we plan to submit a single BLA for the review and approval of this combination of bel- sar with the SCS Microinjector and the laser (s) in our initial target indication of ~~indeterminate lesions and~~ small choroidal melanoma **and indeterminate lesions** , but subsequent indications and delivery systems may require different or additional applications for marketing authorization. The SCS Microinjector was approved by FDA in October 2021 as a constituent of the drug / device combination product XIPERE ® **(triamcinolone acetonide injectable suspension)** . There may be additional regulatory risks for biologic- device combination products. We may experience delays in obtaining regulatory approval of bel- sar given the increased complexity of the review process when approval of the product and a medical device is sought under a single BLA. In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device. Devices are subject to the FDA design control device requirements which comprise among other things, design verification, design validation, and testing to assess performance, cleaning, and robustness. In the **European Union, or** EU, medical devices must be authorized under the EU' s Medical Devices Regulation, which requires compliance with the general safety and performance requirements set forth in such legislation. Delays in or failure of the studies conducted by us, or failure of our company, our collaborators, if any, or our third- party providers or suppliers to maintain compliance with regulatory requirements could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in bel- sar reaching the market. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way in an effort to optimize processes and results. Such changes to a product candidate carry the risk that they will not achieve the intended objectives of optimizing the performance of the candidate. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or ~~the~~ FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue. If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities, or as needed to provide appropriate statistical power for a given trial **. For example, the EMA required additional testing to support drug substance characterization which led to a later than anticipated authorization to commence enrolling patients in our Phase 3 clinical trial under the EU Clinical Trial**

Regulation process . In addition, our competitors may in the future commence clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may choose instead to enroll in clinical trials of our competitors. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit or enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. Our lead indication of ~~primary~~ **early- stage** choroidal melanoma is a rare disease and as such clinical trial recruitment estimates may be inaccurate and such recruitment may take longer than expected. Patient enrollment may be affected by other factors, including: ▪ the severity of the disease under investigation; ▪ clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of bel- sar in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; ▪ the efforts to obtain and maintain patient consents and facilitate timely enrollment in clinical trials; ▪ the ability to monitor patients adequately during and after treatment; ▪ the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion; ▪ competing studies or trials with similar eligibility criteria; ▪ the ability to recruit clinical trial investigators with the appropriate competencies and experience; ▪ reporting of the preliminary results of any of our clinical trials; and ▪ factors we may not be able to control that may limit patients, principal investigators or staff or clinical site availability. We are conducting a clinical trial outside the United States, and we may in the future conduct additional clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials. We are currently conducting a **Phase 3** clinical trial ~~at~~ **and have, or anticipate to have,** sites in **the United States as well as in some or all of the following countries, among others:** Ireland, the UK, Canada, Australia, Austria, Italy, Greece, South Korea, Israel, Germany, France, Spain, Denmark, Sweden, Belgium, **Finland,** and the Czech Republic ~~, and~~ **. We also** may in the future choose to conduct one or more additional clinical trials outside the United States, including in Europe. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U. S. population and the U. S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practices, or GCP, regulations; and (iii) the data may be considered valid without the need for an on- site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well- designed and well- conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. Even if we receive marketing approval for our current or future product candidates in the United States, we may never receive regulatory approval to market our current or future product candidates outside of the United States. We plan to seek regulatory approval of our current or future product candidates outside of the United States. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, we may not obtain approvals in other jurisdictions, and comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among countries and can involve additional product candidate testing and administrative review periods different from those in the United States. The time required to obtain approvals in other countries might differ substantially from that required to obtain the FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding the FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with regulatory requirements in international markets or fail to receive applicable marketing approvals, it would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects. The results of preclinical studies and early clinical trials may not be predictive of future results. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials. Bel- sar and any other product candidates we may develop may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. For example, bel- sar may not be effective at slowing or arresting tumor growth or may not preserve visual acuity in later stage trials. Even if bel- sar successfully slows or completely arrests

tumor growth, this may not result in a reduction in the risk of metastasis. Additionally, any positive results generated in our ongoing clinical trials and preclinical studies would not ensure that we will achieve similar results in larger, pivotal clinical trials or in clinical trials of bel- sar in broader patient populations. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in preclinical testing and earlier- stage clinical trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any product candidate to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of **that product candidate in other indications or patient populations or** any other product candidates then under development and / or cause the FDA or other regulatory authorities to require additional testing before approving **such product candidate or** any other product candidates. Interim, " top- line, " and preliminary **or early** data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary, **early,** interim or top- line data from our clinical trials. These interim updates are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top- line **or early** 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 data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top- line data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. 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. Adverse differences between interim data and final data could materially affect our business, financial condition, results of operations and growth prospects. 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 and our company in general. Further, additional disclosure of interim data by us or by our potential competitors in the future could result in volatility in the price of our common stock. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or top- line data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize our product candidates may be harmed, which could materially affect our business, financial condition, results of operations and growth prospects. Additionally, we may continue to utilize " open- label " trial designs or open- label extensions to our clinical trials in the future. An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open- label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial or extension may not be predictive of future clinical trial results with bel- sar **or any future product candidates** when studied in a controlled environment with a placebo or active control. Bel- sar or any future product candidates may cause or reveal significant adverse events, toxicities or other undesirable side effects which may delay or prevent marketing approval. In addition, if we obtain approval for any of our product candidates, significant adverse events, toxicities or other undesirable side effects may be identified during post- marketing surveillance, which could result in regulatory action or negatively affect our ability to market the product. Adverse events or other undesirable side effects caused by or associated with treatment by bel- sar or our future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or other comparable foreign regulatory authorities. Although bel- sar has been evaluated in clinical trials, unexpected side effects may still arise in our ongoing or any future clinical trials. These side effects have included pigmentary changes around the tumor margin and vision loss. During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large- scale, pivotal clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to: ▪ regulatory authorities may withdraw approvals of such product or require additional warnings on the label; ▪ additional clinical trials or post- approval studies; ▪ we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and / or other elements to assure safe use; ▪ regulatory authorities may require additional warnings or limitations in the labeling, such as a contraindication, limitation of use, or a boxed warning, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product; ▪ we may be subject to regulatory investigations and government enforcement actions; and ▪ our reputation may suffer. Moreover, if bel- sar or any of our future product candidates is associated with undesirable or unexpected side effects in clinical trials, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, which may limit the commercial expectations for the product candidate, even if it is approved. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could materially affect our business, financial condition, results of operations, and growth prospects. We may incur additional costs or experience delays in initiating or completing, or ultimately be unable to complete, the development and commercialization of our product candidates. We may experience delays in initiating or completing our preclinical studies or clinical trials, including as a result of delays in obtaining, or failure to obtain, the FDA' s clearance to initiate clinical trials under future INDs. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of patients on time, or will be completed on schedule, if at all. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including: ▪ we may receive feedback from regulatory authorities that require us to modify the design or implementation of our preclinical studies or clinical trials or to delay or terminate a clinical trial; ▪ regulators or **institutional review board, or** IRBs **,** or ethics committees may delay or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; ▪ we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ▪ preclinical studies or clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product research or development programs; ▪ preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significant results across tumor types or indications; ▪ the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post- treatment follow- up at a higher rate than we anticipate; ▪ our third- party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply to conduct or complete preclinical studies or clinical trials, fail to 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 regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials are being exposed to unacceptable health risks; ▪ the cost of clinical trials of our product candidates may be greater than we anticipate; ▪ 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; ▪ our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and ▪ regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, adverse findings upon an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. 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. Further, the FDA may disagree with our clinical trial design or our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. Moreover, principal investigators for our trials involving bel- sar or any future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory

approval of one or more of our product candidates. Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays also could 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, which would impair our ability to successfully commercialize our product candidates and may significantly harm our business, operating results, financial condition and prospects. Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses. Additionally, our product candidates, if approved, could be subject to post- marketing commitments / requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements. If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, monitoring, 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, establishment registration and listing, compliance with applicable product tracking and tracing requirements, as well as continued compliance with current Good Manufacturing Practices, or cGMPs, and GCPs for any clinical trials that we conduct post- approval. Additionally, under **the Food and Drug Omnibus Reform Act of 2022, or** FDORA, sponsors of approved drugs and biologics must provide ~~6~~ **six** months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product' s ability to be marketed. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: ▪ restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; ▪ manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation; ▪ revisions to the labeling, including limitation on approved uses or the ~~addition~~ **inclusion** of additional warnings, contraindications or other safety information, including boxed warnings; ▪ imposition of a REMS which may include distribution or use restrictions; ▪ requirements to conduct additional post- market clinical trials to assess the safety of the product; ▪ clinical trial holds; ▪ fines, warning letters or other regulatory enforcement action; ▪ refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals; ▪ product seizure or detention, or refusal to permit the import or export of products; and ▪ injunctions or the imposition of civil or criminal penalties. Additionally, the FDA and other regulatory agencies closely regulate the post- approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off- label use. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. If we do not market our medicines for their approved indications, we may be subject to enforcement action for off- label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the ~~FDCA~~ **Federal Food, Drug, and Cosmetic Act** and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. The FDA' s and other regulatory authorities' policies **and interpretations** may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements **, interpretations** or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability **. Moreover, the U. S. Supreme Court' s July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA' s regulations, policies, and decisions may become subject to increasing legal challenges, delays, and / or changes** . We may be unable to obtain ODD for additional indications, or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. ODD must be requested before

submitting an NDA or BLA. In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. After the FDA grants ODD, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has ODD subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if our current product candidates and any future product candidates receive orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product. We have obtained orphan designation for bel- sar for the treatment of uveal melanoma from the FDA and EMA, and we may seek additional ODDs for **bel- sar or** some or all of our ~~current or~~ future product candidates in orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain ODD, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. Similarly, in the EU, the European Commission grants an orphan designation in respect of a product after receiving the opinion of the EMA' s Committee for Orphan Medicinal Products on a designation application. Orphan designation in the EU is granted to products where the sponsor can establish that (1) such product is intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition; (2) either (i) such condition affects no more than ~~5~~ **five** in 10, 000 persons in the EU when the application is made; or (ii) without incentives, it is unlikely that the marketing of the product would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition that has been authorized in the EU, or if such a method exists, the product in question would be of significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor. Generally, if a product with an orphan designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a ten- year period of marketing exclusivity, which precludes the EMA from approving another ~~MA~~ **marketing authorization** application for a similar medicinal product in the same indication for that time period, except in limited circumstances. The EU exclusivity period can be reduced to six years if, at the end of the fifth year, a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable such that market exclusivity is no longer justified. The European Commission introduced a legislative proposal in April 2023 that, if implemented, could reduce the current ten- year marketing exclusivity period in the EU for certain orphan medicines. A breakthrough therapy designation or ~~fast~~ **Fast** ~~track~~ **Track** designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive regulatory approval in the United States. We may seek breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We have obtained ~~fast~~ **Fast** ~~track~~ **Track** designation for bel- sar for the treatment of choroidal melanoma, for the treatment of ~~choroidal metastasis~~ **metastases to the choroid** and for the treatment of NMIBC, and we may seek additional ~~fast~~ **Fast** ~~track~~ **Track** designation for other product candidates we may develop. If a drug or biologic is intended for the treatment of a serious or life- threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for ~~fast~~ **Fast** ~~track~~ **Track** designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive ~~fast~~ **Fast** ~~track~~ **Track** designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw ~~fast~~ **Fast** ~~track~~ **Track** designation if it believes that the

designation is no longer supported by data from our clinical development program. ~~fast~~ **Fast** ~~track~~ **Track** designation alone does not guarantee qualification for the FDA' s priority review procedures. Accelerated approval by the FDA, even if granted for ~~our current~~ **bel- sar** or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval. We may seek accelerated approval of our current or future product candidates using the FDA' s accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life- threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well- controlled post- marketing clinical trials, and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors must also update FDA on the status of these studies, and under FDORA, the FDA has increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post- approval studies fail to verify the drug' s predicted clinical benefit. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval. The FDA' s agreement to a Special Protocol Assessment **, or SPA,** with respect to the study design of our global Phase 3 trial of bel- sar for the treatment of early- stage choroidal melanoma does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a successful review or approval process. We ~~have~~ obtained agreement from the FDA on the design and planned analysis of our global Phase 3 trial of bel- sar for the treatment of early- stage choroidal melanoma through an SPA. An SPA agreement documents FDA' s agreement that the design and planned analysis of a study can adequately address objectives in support of a regulatory submission. However, final determinations for marketing application approval are made after complete review of a marketing application and are based on the entire data in the application. The FDA' s SPA process is designed to facilitate the FDA' s review and approval of drugs and biologics by allowing the FDA to evaluate the proposed design and size of certain clinical or animal studies, including clinical trials that are intended to form the primary basis for determining a product candidate' s efficacy. The FDA ultimately assesses whether specific elements of the protocol design of the trial, such as entry criteria, dose selection, endpoints and / or planned analyses, are acceptable to support a regulatory submission. Although the FDA may agree to an SPA, an SPA agreement does not guarantee approval of a product. Even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding by the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol. Generally, such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. Moreover, if the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval of bel- sar for the treatment of **small choroidal melanoma and** indeterminate lesions ~~and choroidal melanoma~~ . Risks Related to Our Reliance on Third Parties We ~~expect to~~ rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and **expect to continue to do so, and** those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing. We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, central reading centers, medical institutions and clinical investigators, to conduct some aspects of our research, preclinical testing and clinical trials. We **are using** ~~plan to use~~ a clinical CRO for the pivotal trial for bel- sar for the treatment of **early- stage** choroidal melanoma. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, our product development activities would be delayed. Our reliance on these third parties for research and development activities reduces our control over these activities, but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, as well as the applicable legal, regulatory and scientific standards. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We are also required to register ongoing clinical trials and to post the results of completed clinical trials on a government- sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Due to the rarity of ocular melanomas, we may engage clinical trial sites that have little experience in the conduct of clinical trials under GCPs. Even though we train the clinical trial sites, monitor the activities, and perform quality audits to assess and ensure compliance, we cannot ensure such compliance.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other biological product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue. We currently rely on third- party CDMOs for the production of clinical supply of bel- sar and may continue to rely on CDMOs for the production of commercial supply of bel- sar, if approved. This reliance on CDMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts. We currently do not have any manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for future preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We are currently reliant on a single source for each of our regulatory starting materials, drug substance and drug product manufacturing for bel- sar. We or our third- party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient, or API, necessary to produce bel- sar and future product candidates we may develop in the quantities needed for our clinical trials or, if bel- sar or any future product candidates we may develop are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or APIs, including shortages caused by the purchase of such raw materials or API, by our competitors or others. Even if raw materials or API are available, we may be unable to obtain sufficient quantities at an acceptable cost or quality. The failure by us or our third- party suppliers or manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of bel- sar or any future product candidates we may develop could delay, prevent or impair our development efforts and may have a material adverse effect on our business. To date, we have only encountered minor delays in our manufacturing process due to a supply chain constraint with one of our vendors. Reliance on third- party manufacturers may expose us to different risks than if we were to manufacture clinical or commercial supply of our product candidates ourselves. The facilities used by third- party manufacturers to manufacture bel- sar or any future product candidates must be authorized by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third- party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third- party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. Some of our contract manufacturers may not have produced a commercially- approved product and, therefore, may not have obtained the requisite FDA approvals to do so. In addition, we have no control over the ability of third- party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Finding new CDMOs or third- party suppliers involves additional cost and requires our management' s time and focus. In addition, there is typically a transition period when a new CDMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. Additionally, any changes implemented by a new CDMO could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of bel- sar and future product candidates and jeopardize our ability to commence product sales and generate revenue. As part of their manufacture of our product candidates, our CDMOs and third- party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CDMO or third- party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or proprietary rights of others in the course of providing services to us, we may have to find alternative CDMOs or third- party suppliers or defend against applicable claims, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. 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, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third- party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: ▪ failure of third- party manufacturers to comply with regulatory requirements and maintain quality assurance; ▪ breach of the manufacturing agreement by the third- party manufacturers; ▪ failure to manufacture our product according to our specifications; ▪ lack of qualified backup suppliers for those components or materials that are currently purchased from a sole or single source supplier; ▪ failure to manufacture our product according to our schedule or at all; ▪ production difficulties caused by unforeseen events that may delay the availability

of one or more of the necessary raw materials or delay the manufacture of bel- sar or any future product candidates for use in clinical trials or for commercial supply; ▪ supply or service disruptions or increased costs that are beyond our control; ▪ misappropriation of our proprietary information, including our trade secrets and know- how; and ▪ termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. Bel- sar and any other product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time- consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third- party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or on terms acceptable to us. Our current and anticipated future dependence upon others for the manufacture of bel- sar or any other future product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Risks Related to Commercialization If bel- sar or any future product candidates do not achieve broad market acceptance, the revenue that we generate from their sales may be limited, and we may never become profitable. We have never commercialized a product candidate for any indication. Even if bel- sar and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third- party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not become profitable or may be significantly delayed in achieving profitability. Market acceptance of bel- sar and any future product candidates by the medical community, patients and third- party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch, from existing therapies even when new and potentially more effective or safer treatments enter the market. If public perception is influenced by claims that the use of VDCs is unsafe, whether related to our or our competitors' products, our products may not be accepted by the general public or the medical community. In addition, training clinicians to properly use bel- sar or any future product candidate that requires a similar laser and microinjector may create reluctance by clinicians to adopt our products, potentially adversely affecting our future sales and marketing efforts. Furthermore, such training increases our costs to generate sales associated with any such product. Future adverse events in targeted oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. Efforts to educate the medical community and third- party payors on the benefits of bel- sar and any future product candidates may require significant resources and may not be successful. If bel- sar or any future product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of bel- sar and any future product candidates will depend on a number of factors, including: ▪ the efficacy of bel- sar and our VLP technology, and any future product candidates; ▪ the prevalence and severity of adverse events associated with bel- sar and any future product candidates or those products with which they may be co- administered; ▪ the clinical indications for which bel- sar are approved and the approved claims that we may make for the products; ▪ limitations or warnings contained in the product' s FDA- approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for bel- sar and any future product candidates that may be more restrictive than other competitive products; ▪ changes in the SoC for the targeted indications for bel- sar and any future product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained; ▪ the relative convenience and ease of administration of bel- sar and any future product candidates and any products with which they are co- administered; ▪ the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies; ▪ the availability of adequate coverage or reimbursement by third- party payors, including government healthcare programs such as Medicare and Medicaid and other healthcare payors; ▪ the price concessions required by third- party payors to obtain coverage; ▪ the perception of physicians, patients, third- party payors and others in the medical community of the relative safety, efficacy, convenience, effect on quality of life and cost effectiveness of bel- sar compared to those of other available treatments; ▪ the willingness of patients to pay out- of- pocket in the absence of adequate coverage and reimbursement; ▪ the extent and strength of our marketing and distribution of bel- sar and any future product candidates; ▪ the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved; ▪ distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to bel- sar and any future product candidates or to which we agree as part of a REMS or voluntary risk management plan; ▪ the timing of market introduction of bel- sar and any future product candidates, as well as competitive products; ▪ our ability to offer bel- sar and any future product candidates for sale at competitive prices; ▪ the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ▪ the extent and strength of our third- party manufacturer and supplier support; ▪ the publicity concerning our bel- sar or competing products and treatments; ▪ the actions of companies that market any products with which bel- sar and any future product candidates may be co- administered; ▪ the approval of other new products; ▪ adverse publicity about bel- sar and any future product candidates or any products with which they are co- administered, or favorable publicity about competitive products; and ▪ potential product liability claims. We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product

candidates, we may not be able to generate product revenue. We have never commercialized a product candidate and we currently have no sales, marketing or distribution capabilities and have no experience in marketing products. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidate and undertaking preclinical studies and clinical trials of our product candidate. We intend to develop an in- house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. We may not be successful in transitioning from a company with a development focus to a company capable of supporting commercial activities. In addition to establishing internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. Further, if we enter into arrangements with third parties to perform sales and marketing services, our product revenues, if any, may be lower than if we were to market and sell any products that we develop ourselves. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. Furthermore, developing a sales and marketing organization requires significant investment, is time- consuming and could delay the launch of our product candidate. We may not be able to build an effective sales and marketing organization in the United States, the EU or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidate, we may have difficulties generating revenue from them. There can be no assurance that we will be able to develop in- house sales and distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product in the United States or overseas. We may face competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do. The biopharmaceutical industry is characterized by intense competition and rapid innovation. While we are not aware of anyone currently developing a treatment for **early- stage** choroidal melanoma, in the future our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than us. There are multiple companies that have drugs in clinical development for the treatment of NMIBC ~~that are unresponsive to BCG~~ , such as **Johnson & Johnson** ~~Sesen Bio, Inc., FerGene, Inc.~~ , UroGen Pharma Ltd., CG Oncology, Inc. ~~and~~ **,** ImmunityBio, Inc **. and Ferring Pharmaceuticals** . Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our potential competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well- established sales forces. Smaller or early- stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in- license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaboration partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products, which may reduce or eliminate our commercial opportunity. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement. Even if we obtain regulatory approval of our product candidates, the availability and price of our potential future competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see **the section of our Annual Report on Form 10- K for the year ended December 31, 2024 titled** " Business — Competition. " Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives, which would harm our business. In the United States and markets in other countries, patients generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. For more information, see **the section of our Annual Report on Form 10- K for the year ended December 31, 2024 titled** " Business — Government Regulation — Coverage and Reimbursement. " 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 limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs, or VA, hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our

products, if approved. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. If the market opportunity for bel- sar is smaller than we estimate or if any regulatory 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, possibly materially. The incidence and prevalence for target patient populations of bel- sar and any future product candidates has not been established with precision. Bel- sar is a VDC product candidate being developed for the first line treatment of ~~primary~~ **early- stage** choroidal melanoma. Our projections of both the number of people who have choroidal melanoma, as well as additional ocular oncology and bladder cancer indications, are based on our estimates. The total addressable market opportunity will ultimately depend upon, among other things, the patient criteria included in the final label, the indications for which bel- sar is approved for sale, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with choroidal melanoma, ~~choroidal metastasis~~ **metastases to the choroid** , and ~~NMIBC~~ **bladder cancer** for which bel- sar may be approved as treatment may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Bel- sar is our only product candidate and therefore our business is dependent on the market opportunity for our product. Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. For more information, see **the section of our Annual Report on Form 10- K for the year ended December 31, 2024 titled** " Business ~~—~~ Government Regulation ~~—~~ Health Care Laws and Regulations. " Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many states in the United States have adopted laws similar to the federal Anti- Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and / or the Pharmaceutical Research and Manufacturers of America' s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the **General Data Protection Regulation, or** GDPR, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by **the Health Insurance Portability and Accountability Act, or** HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected. Current and future healthcare legislative reform measures may have a material adverse effect on our business and results of operations. The United States and many foreign jurisdictions have enacted and / or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay regulatory approval of our current or future product candidates or any future product candidates, restrict or regulate post- approval activities, and affect our ability to profitably sell a product for which we obtain regulatory approval. Changes in laws, regulations, statutes or the interpretation of existing laws and regulations could impact our business in the future by requiring, for example: (i) changes to

our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For more information, see **the section of our Annual Report on Form 10- K for the year ended December 31, 2024 titled** " Business — Government Regulation — Health Care Reform & Legislative Updates. " In the United States, there have been, and continue to be, a significant number of legislative initiatives to contain healthcare costs. The United States has also sought to implement **legislation** at the state level, **and** individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business. Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect ~~:~~. ▪ the demand for our current or future product candidates, if we obtain regulatory approval; ▪ our ability to set a price that we believe is fair for our products; ▪ our ability to obtain coverage and reimbursement approval for a product; ▪ our ability to generate revenue and achieve or maintain profitability; ▪ the level of taxes that we are required to pay; and ▪ the availability of capital. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. Risks Related to Our Intellectual Property Our ability to compete may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantage. Our commercial success depends upon obtaining and maintaining proprietary rights to our intellectual property estate, including rights relating to our technology platform using HPV-derived VLPs to target tumors and VDCs like bel- sar, as well as successfully defending these rights against third- party challenges and successfully enforcing these rights to prevent third- party infringement. We will only be able to protect bel- sar or a future product candidate derived from our platform from unauthorized use by third parties to the extent that valid and enforceable patents cover it. Our ability to maintain patent protection for bel- sar or a future product candidate is uncertain due to a number of factors, including that: ▪ others may design around our patent claims to produce competitive technologies, products or methods that fall outside of the scope of our patents; ▪ we may not obtain patent protection in all jurisdictions that may eventually provide us a significant business opportunity; and ▪ any patents issued to us may be successfully challenged by third parties. Even with our patents covering bel- sar, we may still not be able to make use or sell bel- sar or a future product candidate because of the patent rights of others. Others may have filed patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully commercialize bel- sar or a future product candidate. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges 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 products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Obtaining and maintaining a patent portfolio entails significant expense, including periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications. These expenditures can be at numerous stages of prosecuting patent applications and over the lifetime of maintaining and enforcing issued patents. We may or may not choose to pursue or maintain protection for particular intellectual property in our portfolio. If we choose to forgo patent protection or to allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Furthermore, we employ reputable law firms and other professionals to help us comply with the various procedural, documentary, fee payment and other similar provisions we are subject to and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Legal action that may be required to enforce our patent rights can be expensive and may involve the diversion of significant management time. There can be no assurance that we will have sufficient financial or other resources to file and pursue infringement claims, which typically last for years before they are concluded. In addition, these legal actions could be unsuccessful and result in the invalidation of our patents, a finding that they are unenforceable or a requirement that we enter into a licensing agreement with or pay monies to a third party for use of technology covered by our patents. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or have used them without authorization, due to the associated expense and time

commitment of monitoring these activities. If we fail to successfully protect or enforce our intellectual property rights, our competitive position could suffer, which could harm our results of operations. We may need to license 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 rights, including patent rights, that are important or necessary to the development of bel- sar or any future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize bel- sar or any future product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed. The growth of our business may depend in part on our ability to acquire, in- license or use third- party proprietary rights. We may be unable to acquire or in- license any such proprietary rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. We rely on intellectual property licensed from third parties. We face risks with respect to such reliance, including the risk that, if we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We are a party to a number of intellectual property license agreements that are important to our business. Our existing license agreements impose on us various diligence, milestone payment, royalty and other obligations. If we fail to comply with any of our obligations under these agreements, or we are subject to a bankruptcy, our licensors may have the right to terminate the license, in which event we would not be able to market any products covered by the license. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including: ▪ the scope of rights granted and related obligations under the license agreement and other interpretation- related issues; ▪ our licensor' s right to license or sublicense patent and other rights to us, and whether and the extent to which the right is retained by a third party; ▪ whether and the extent to which our technology infringes on intellectual property of the licensor that is not subject to the licensing agreement; ▪ our right to sublicense patent and other rights to third parties under collaborative development relationships; ▪ our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of bel- sar or any future product candidates, and what activities satisfy those diligence obligations; and ▪ the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. In addition, disputes may arise regarding the payment of the royalties due to licensors in connection with our exploitation of the rights we license from them. Licensors may contest the basis of royalties we retained and claim that we are obligated to make payments under a broader basis. Such disputes may be costly to resolve and may divert management' s attention away from day- to- day activities. In addition to the costs of any litigation we may face, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors. If disputes over intellectual property that we have licensed from third parties prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we or our collaborators may be unable to successfully manufacture and commercialize bel- sar or a future product candidate. If we fail to comply with our obligations under the license agreements, our licensors may have the right to terminate these agreements, in which event we might not be able to manufacture or market bel- sar or a future product candidate. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries under similar legislation with respect to ~~our~~ bel- sar or a future product candidate, thereby potentially extending the term of marketing exclusivity for such product, our business may be harmed. In the United States, a patent that covers an FDA- approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of the FDA marketing approval of our product candidates, one or more of our owned, co- owned, or in- licensed U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Act. The Hatch- Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The Hatch- Waxman Act allows a maximum of one patent to be extended per FDA- approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the EU, bel- sar or a future product candidate may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market

competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial. Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position. The patent positions of biopharmaceutical and biotechnology companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the U. S. Patent and Trademark Office, or the USPTO, and its foreign counterparts are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. The U. S. patents and patent applications may also be subject to interference or derivation proceedings, and the U. S. patents may be subject to reexamination proceedings, post- grant review and / or inter partes review in the USPTO. International patents may also be subject to opposition or comparable proceedings in the corresponding international patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, reexamination, post- grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes. Furthermore, even if not challenged, our patents and patent applications may not prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to bel- sar or a future product candidate is threatened, it could dissuade companies from collaborating with us to develop, and could threaten our or their ability to successfully commercialize, bel- sar or a future product candidate. In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology without providing any compensation to us ~~,~~ **and** may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as the U. S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk. Our commercial success depends upon our ability to develop, manufacture, market and sell bel- sar or a future product candidate without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the biotechnology industry is common, including patent infringement lawsuits, interferences, oppositions, reexamination proceedings, post- grant review, and / or inter partes review before the USPTO and corresponding international patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property- dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. As a result of any patent infringement claims, or in order to avoid any potential infringement claims, we may choose to seek, or be required to seek, a license from the third- party, which may require payment of substantial royalties or fees, or require us to grant a cross- license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing bel- sar or a future product candidate, or forced to modify bel- sar or a future product candidate, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our technology or product candidates so that we no longer infringe the third- party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Further, if a patent infringement suit is brought against us or our third- party service providers, our development, manufacturing or sales activities relating to bel- sar or a future product candidate that is the subject of the suit may be delayed or terminated. In addition, defending such claims may cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third- party' s patent rights. These damages potentially could include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. In addition, if the breadth or strength of protection provided by the patents and patent applications we own or in- license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. We may in the future be subject to third- party claims and similar adversarial proceedings or litigation in other jurisdictions regarding our infringement of the patent rights of third parties. Even if such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to further develop or commercialize bel- sar or a future product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering our technology or a product candidate, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and Europe, defendant counterclaims alleging invalidity or

unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non- enablement. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part of the patent protection on bel- sar or a future product candidate. We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection. Filing, prosecuting and defending patents on bel- sar or a future product candidate in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the **United States** ~~U. S.~~, or from selling or importing products made using our inventions in and into the **United States** ~~U. S.~~ or other jurisdictions. We have and have applied for patents in those countries where we intend to make, have made, use, offer for sale or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but where our ability to enforce our patent rights is not as strong as in the United States. These products may compete with any products that we may develop, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition. The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we chose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. As a result, many companies have encountered significant difficulties in protecting and defending intellectual property rights in certain jurisdictions outside the United States. Such issues may make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, subject our patents to the risk of being invalidated or interpreted narrowly, subject our patent applications to the risk of not issuing or 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 to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If we or our licensors are unable to protect the confidentiality of the proprietary information related to our product or process, our business and competitive position would be harmed. We and our licensors rely on confidentiality agreements to protect unpatented know- how, technology and other proprietary information related to our product and process, to maintain our competitive position. For example, our licensor **Rakuten (previously** LI- COR **)** maintains its manufacture of IRDye 700DX ® dye molecules (used in bel- sar) as a trade secret. Trade secrets and know- how can be difficult to protect. In particular, the trade secrets and know- how in connection with our development programs and other proprietary technology we may develop may over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel with scientific positions in academic and industry. We seek to protect our proprietary information, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated proprietary information is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or are unwilling to protect trade secrets. We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing bel- sar. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our therapeutic programs and other proprietary technologies we may develop. Such an outcome could have a materially adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Moreover, our competitors may independently develop knowledge, methods and know- how equivalent to our proprietary information. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our proprietary information 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 any of our proprietary information were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached or subject to unauthorized access and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time- consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any cybersecurity incident or breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case 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, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Risks Related to our Business and Industry If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to pursue our business strategy will be impaired, could result in loss of markets or market share and could make us less competitive. Our ability to compete in the highly competitive biopharmaceutical industries depends upon our ability to attract, manage, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements for these individuals could harm our business. 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. Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, in a timely manner or at all. In particular, we have experienced a very competitive hiring environment in the Boston area, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we have to offer. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity incentive awards that vest over time. The value to employees of restricted stock awards and stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams are at- will employees and may terminate their employment with us on short notice. We do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees. Given the stage of our programs and our plans to expand operations, our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior personnel across our organization. Inadequate funding **, substantial changes in leadership, personnel, policies** ~~for -~~ **or** ~~the FDA~~ **priorities of** , **or** ~~the SEC and~~ other **disruptions at federal** ~~government~~ **governmental** agencies, including from government shut downs, **layoffs of federal agency employees** or other disruptions to these agencies' operations, **funding or staffing,** could hinder their ability to hire and retain key leadership and other personnel, prevent **, delay, or hinder the research, development or commercialization of** 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, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. **Currently, federal agencies in the United States are operating under a continuing resolution that is set to expire on September 30, 2025.** Disruptions **in staffing, funding or operations** at the FDA **, SEC, NIH, USPTO** and other **government** agencies **, including a potential or actual government shutdown or any changes and / or additional policies or regulations relating to federal agencies as a result of the new U. S. presidential administration,** may also **prevent, delay** ~~slow the time necessary for -~~ **or hinder the research, development or commercialization of** new ~~product~~ **products , including** ~~candidates to be reviewed --~~ **review** and / or ~~approved~~ **approval of new products** by necessary government agencies, **any of** which would adversely affect our business. **For example, over the last several years, the U. S. government has shut down at times and certain federal agencies, such as the FDA, have had to furlough critical employees and stop critical activities.** If a prolonged government shutdown occurs, **including as a result of reaching the debt ceiling,** it could significantly impact the ability of **federal agencies to perform normal business functions on which the operation of our business may rely, including** the FDA **' s ability** to timely review and process our regulatory submissions, **any of** which could have a material adverse effect on our business. Further, future government shutdowns **or other disruption of the operations of federal agencies** could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of

hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and ~~wastes~~ **waste** . We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. Changes in tax laws or in their implementation or interpretation may adversely affect us or our investors. The rules dealing with the U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made and changes are likely to continue to occur in the future. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the **United States** ~~U. S.~~ will be capitalized and amortized, which may have an adverse effect on our cash flow. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, 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 or mitigate any adverse effects of changes in tax law or in the interpretation thereof. Our internal information technology systems, or those of our third- party CROs, contractors, consultants or others who process sensitive information on our behalf, may fail or suffer cybersecurity incidents or breaches, loss or leakage of data and other compromises, any of which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing such information, expose us to liability or otherwise adversely affect our business. In the ordinary course of our business, we may collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information (including health information). We have established safeguards to do so in a secure manner in an effort to maintain the confidentiality, integrity and availability of such information. We also have outsourced certain of our operations to third parties, and as a result, we manage a number of third parties who have access to our information. Despite the implementation of security measures, our internal computer systems and infrastructure, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access and misuse, cyberattacks by sophisticated nation- state and nation- state supported actors or by malicious third parties (including the deployment of harmful malware (such as malicious code, viruses and worms), natural disasters, global pandemics, fire, terrorism, war and telecommunication and electrical failures, fraudulent activity, as well as cybersecurity incidents or breaches from inadvertent or intentional actions (such as error or theft) by our employees, contractors, consultants, business partners, and / or other third parties, phishing attacks, ransomware, denial- of- service attacks, social engineering schemes (including phishing attacks) and other means that affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure as well as lead to unauthorized access, disclosure, misuse or acquisition of information. **We, and our service providers, have from time to time and may in the future continue to experience threats and cybersecurity incidents relating to our and our third- party vendors' information systems.** Cyberattacks generally are increasing in their frequency, sophistication and intensity. The techniques used to sabotage or to obtain unauthorized access to our information technology systems or those upon whom we rely on to process our information change frequently, and we may be unable to anticipate such techniques or implement adequate preventative measures or to stop or to adequately address cybersecurity incidents or breaches in all instances. The recovery systems, security protocols, network protection mechanisms and other security measures that we have integrated into our information technology systems, which are designed to protect against, detect and minimize cybersecurity incidents or breaches, may not be adequate to prevent or detect or adequately address service interruption, system failure or data loss. Significant disruptions of our information technology systems or cybersecurity incidents could adversely affect our business operations and / or result in the loss, misappropriation, and / or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information including health information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, as a result of increased hybrid work, a significant number of our employees and partners are working remotely, which increases the risk of a cybersecurity incident or breach or other data and cybersecurity issues. To the extent that any disruption or cybersecurity incident or breach results in a loss of, or damage to, our data or applications, or inappropriate disclosure or misuse of or access to confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed. We may also be required to comply with laws, regulations, rules, industry standards, and other legal obligations that require us to maintain the security of personal data. We may also have contractual and other legal obligations to notify collaborators, our clinical trial participants, or other relevant stakeholders of cybersecurity incidents and breaches. Failure to prevent or mitigate cyberattacks could result in unauthorized access to data, including personal data. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of cybersecurity incidents or breaches involving certain types of data. Such disclosures are costly, could lead to negative publicity, may cause our collaborators or other relevant stakeholders to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and / or alleviate problems

caused by the actual or perceived cybersecurity incident or breach. In addition, the costs to respond to a cybersecurity event or to mitigate any identified security vulnerabilities could be significant, including costs for remediating the effects of such an event, paying a ransom, restoring data from backups, and conducting data analysis to determine what data may have been affected by the cybersecurity incident or breach. In addition, our efforts to contain or remediate a cybersecurity incident or any vulnerability exploited to cause an incident may be unsuccessful, and efforts and any related failures to contain or remediate them could result in interruptions, delays, harm to our reputation, and increases to our insurance coverage. In addition, litigation resulting from cybersecurity incidents or breaches may adversely affect our business. Unauthorized access to our information technology systems or infrastructure could result in litigation with our collaborators, our clinical trial participants, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management' s time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation, which could have an adverse effect on our business. If a cybersecurity incident or breach were to occur and the confidentiality, integrity or availability of our data or the data of our collaborators were disrupted, we could incur significant liability, which could negatively affect our business and damage our reputation. Furthermore, we may not have adequate insurance coverage or otherwise **to** protect us from, or adequately mitigate, liabilities or damages. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co- insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. We are, or may become, subject to stringent and changing privacy and information security laws, regulations, standards, policies and contractual obligations related to data privacy and security. Our actual or perceived failure to comply with such data privacy and security obligations could lead to government enforcement actions (which could include civil or criminal fines or penalties), a disruption of our clinical trials or commercialization of our products, private litigation, changes to our business practices, increased costs of operations, and adverse publicity that could otherwise negatively affect our operating results and business. Compliance or the failure to comply with such obligations could increase the costs of our products, could limit their use or adoption, and could otherwise negatively affect our operating results and business. Regulation of data (including personal and clinical trial data) is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. Moreover, we are subject to the terms of our privacy and security policies, representations, certifications, standards, publications, contracts and other obligations to third parties related to data privacy, security and processing. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products, affect our or our collaborators' ability to offer our products in certain locations, cause regulators to reject, limit or disrupt our clinical trial activities, result in increased expenses, reduce overall demand for our products, and make it more difficult to meet expectations of relevant stakeholders. We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations including, without limitation, laws that regulate personal data such as health data. For example, in the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state personal information laws (e. g., the California Consumer Privacy Act of 2018, or CCPA), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations (e. g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure and protection of health- related and other personal data. These laws and regulations could apply to our operations, the operations of our collaborators, or other relevant stakeholders upon whom we depend. In addition, we may obtain personal data (including health information) from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by ~~HITECH~~ **the Health Information Technology for Economic and Clinical Health Act** . Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. Additionally, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. ~~The~~ **At the state level, the** CCPA ~~, which went into effect on January 1, 2020,~~ established a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, **providing** ~~establishing new~~ data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches **. The law also provides California residents with the ability to limit use of certain sensitive information, establishes restrictions on the retention of personal data, and established a new state regulatory agency, the California Privacy Protection Agency, to implement and enforce the legislation** . Although there are limited exemptions for protected health information covered under HIPAA and clinical trial data, the CCPA may increase our compliance costs and potential liability. ~~The CCPA was expanded on January 1, 2023, when the California Privacy Rights Act of 2020, or CPRA, became operative. The amendments introduced by the CPRA expanded the scope of the CCPA in a number of ways, including by providing California residents the ability to limit use of certain sensitive information, establishing restrictions on the retention of personal data, expanding the types of data breaches subject to the CCPA' s private right of action and establishing a California Privacy Protection Agency to implement and enforce the legislation.~~ Similar comprehensive consumer privacy laws have been

passed in numerous other states and a number of other states have proposed new privacy laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. In addition, laws in all 50 U. S. states require businesses to provide notice to individuals if certain of their personal information has been disclosed as a result of a qualifying data breach or cybersecurity incident. There are also states that are specifically regulating health information. For example, Washington state recently ~~passed~~ **enacted** a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and / or passed legislation that regulates the privacy and / or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U. S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted. These laws demonstrate our vulnerability to the evolving regulatory environment related to personal data. As we expand our operations, these and similar laws may increase our compliance costs and potential liability. Foreign data protection laws, such as, without limitation, the EU GDPR, the EU member state implementing legislation, and the UK GDPR, may also apply to health- related and other personal data that we process, including, without limitation, personal data relating to clinical trial participants. The GDPR imposes strict obligations on the ability to process health- related and other personal data, including in relation to security (which requires the adoption of administrative, physical and technical safeguards designed to protect such information), collection, use and transfer ~~or~~ **of** personal data. These obligations include, without limitation, several **transparency** requirements relating ~~to transparency related~~ to communications with data subjects regarding the processing of their personal data, ensuring an appropriate legal basis or conditions applies to the processing of personal data, limitations on the retention of personal data, increased requirements pertaining to health data, notification of data processing obligations or security incidents to the competent national data protection authorities and / or data subjects, the security and confidentiality of the personal data, various rights that data subjects may exercise with respect to their personal data, and strict rules and restrictions on the international transfer of personal data. The GDPR imposes strict rules on the transfer of personal data out of the EEA and UK to other regions outside the EEA / UK, or third countries, that have not been deemed to offer " adequate " privacy protections by the competent data protection authorities, including the United States in certain circumstances, unless a derogation exists or adequate international transfer safeguards (for example, the European Commission approved Standard Contractual Clauses, or the EU SCCs, and the UK International Data Transfer Agreement / Addendum, or the UK IDTA) are put in place. Where relying on the EU SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments on the transfers made pursuant to the EU SCCs and UK IDTA, on a case- by- case basis, to ensure the law in the recipient country provides " essentially equivalent " protections to safeguard the transferred personal data as provided in the EEA and UK, and may be required to adopt supplementary measures if this standard is not met. Further, the EU and United States have adopted its adequacy decision for the EU- U. S. Data Privacy Framework, or the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA and UK personal data is located and which service providers we can utilize for the processing of EEA and UK personal data. Any inability to process or transfer personal data from the EEA to the United States in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position. Although the UK is regarded as one of the third countries under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EEA member states to the UK without additional safeguards. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government has introduced a Data ~~Protection~~ **(Use** and ~~Digital Information~~ **Access)** Bill, or the UK Bill, into the UK legislative process. The aim of the UK Bill is to reform the UK' s data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime. In addition, EEA Member States have adopted national laws to implement the GDPR that may partially deviate from the GDPR. Further, the competent authorities in the EEA Member States interpret GDPR obligations slightly differently from country to country (particularly in relation to the processing of health data) and therefore we do not expect to operate in a uniform legal landscape in the EEA. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA. The increase of foreign privacy and security legal frameworks with which we must comply, increases our compliance burdens and exposure to substantial fines and penalties for non- compliance. For example, under the GDPR, entities that violate the GDPR can face fines of up to the greater of 20 million euros (£ 17. 5 million under UK GDPR) or 4 % of their worldwide annual turnover, or revenue ~~,~~. Additionally, regulators could prohibit our use of personal data subject to the GDPR. The GDPR also

confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from infringement of the GDPR. The GDPR has increased our responsibility and potential liability in relation to personal data that we process, requiring us to put in place additional mechanisms to comply with the GDPR and other foreign data protection requirements. We may also publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal data and / or other confidential information. Although we endeavor to comply with our published policies and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractors fail to comply with our published policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices **. Additionally in the EU, the NIS 2 Directive (NIS 2) is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EU within scope of the legal framework. It extends to additional sectors and expands the list of in- scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in- scope organization' s compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant EU Member State. EU Member States had until 17 October 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EU is currently fragmented and uncertain. To the extent we are subject to NIS 2, we will require additional investment of our resources in compliance programs and will potentially come under greater regulatory scrutiny. Under NIS 2 companies may be subject to administrative fines of up to the higher amount of € 10 million or 2 % of worldwide turnover. Regulators and legislators in the United States are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, Executive Order 14117 of February 28, 2024, Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government- Related Data by Countries of Concern as implemented by Department of Justice regulations issued in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and / or civil sanctions, and may result in exclusion from participation in federal and state programs** . Compliance with U. S. federal and state as well as foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management' s time and / or divert resources from other initiatives and projects. Failure, or perceived failure, to comply with federal, state and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties, fines or penalties), private litigation, a diversion of management attention, adverse publicity and negative effects on our operating results and business. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or data protection obligations related to information security, cybersecurity incidents or data breaches. Moreover, clinical trial participants or patients about whom we or our collaborators obtain information, as well as the providers who share this information with us, may limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, contracts or privacy notices or breached other obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and make it more difficult to meet expectations of or commitments to our relevant stakeholders. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data. Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. In addition, our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third- party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. We also expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research,

development and compliance in this area. For example, the EU' s Artificial Intelligence Act, or the AI Act, the world' s first comprehensive AI law, is ~~anticipated to enter~~ **entered** into force in Spring 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems **. Likewise, in the United States, several states, including Colorado and California, passed laws that will take effect in 2026, to regulate various uses of artificial intelligence, including to make consequential decisions. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to meet higher standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non- compliance** . If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, pandemics and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third- party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption. Any future acquisitions, in- licensing or strategic partnerships may increase our capital requirements, dilute our stockholders, divert our management' s attention, cause us to incur debt or assume contingent liabilities and subject us to other risks. We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including: ▪ increased operating expenses and cash requirements; ▪ the assumption of indebtedness or contingent liabilities; ▪ the issuance of our equity securities which would result in dilution to our stockholders; ▪ assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel; ▪ the diversion of our management' s attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership; ▪ spend substantial operational, financial and management resources in integrating new businesses, technologies and products; ▪ retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; ▪ risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and ▪ our inability to generate revenue from acquired intellectual property, technology and / or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs. In addition, if we undertake such a transaction, we may incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. We or the third parties upon whom we depend on may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. For example, following Hurricane Maria, shortages in production and delays in a number of medical supplies produced in Puerto Rico resulted, and any similar interruption due to a natural disaster affecting us or any of our third- party manufacturers could materially delay our operations. We expect to significantly expand our organization, including building sales and marketing capability and creating additional infrastructure to support our operations as a public company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing and finance and accounting. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert or stretch our management and business development resources in a way that we may not anticipate. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any current or future product candidates that we may develop. We will face an inherent risk of product liability exposure related to the testing of our current or future product candidates in human clinical trials and will face

an even greater risk if we commercially sell any current or future product candidates that we may develop. Claims could also be asserted under the state consumer production acts. If we cannot successfully defend ourselves against claims that our current or future product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ▪ decreased demand for any current or future product candidates that we may develop; ▪ injury to our reputation and significant negative media attention; ▪ withdrawal of clinical trial participants; ▪ significant costs to defend the related litigation; ▪ a diversion of management' s time and resources; ▪ substantial monetary awards to trial participants or patients; ▪ product recalls, withdrawals or labeling, marketing or promotional restrictions; ▪ loss of revenue; ▪ a decline in our stock price; and ▪ the inability to commercialize any current or future product candidates that we may develop. **While we** ~~We do not yet~~ maintain product liability insurance, ~~and~~ we anticipate that we will need to increase our insurance coverage ~~when~~ **as** we ~~begin~~ **conduct additional** clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain product liability insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations. We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; the U. S. federal and state fraud and abuse laws, data privacy and security laws and other similar non- United States laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. 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 be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other United States federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non- compliance, imprisonment, other sanctions, 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 and our results of operations. Risks Related to Our Common Stock If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval. Based on the beneficial ownership of our common stock as of December 31, ~~2023~~ **2024** , our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially owned approximately ~~51~~ **52** . ~~0~~ **6** % of our outstanding common stock. As a result, these stockholders, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. 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, or the Code, if a corporation undergoes an " ownership change " (generally defined as a greater than 50 percentage point 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, or NOL, 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 subsequent shifts in our stock ownership, some of which are outside our control. Our gross operating losses and tax credits may also be impaired or restricted under state law. As of December 31, ~~2023~~ **2024** , we had federal gross operating loss carryforwards of approximately $ ~~174~~ **209** . ~~4~~ **8** million, state gross operating loss carryforwards of $ ~~148~~ **183** . ~~5~~ **6** million, and foreign gross operating loss carryforwards of $ 0. ~~1~~ **7** million. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating the U. S. federal and state taxable income. As a result, the amount of the gross operating loss and tax credit carryforwards presented in our financial statements could be limited

and may expire unutilized. Under current law, unused U. S. federal gross operating loss carryforwards generated in taxable years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. For taxable years beginning after December 31, 2020, however, the deductibility of such U. S. federal NOLs is limited to 80 % of our taxable income in such taxable years. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. ~~For a further description of our dividend policy, please refer to the section titled " Dividend Policy. "~~ We may be subject to securities litigation, which is expensive and could divert management attention. The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including: ▪ variations in the level of expense related to the ongoing development of bel- sar or future development programs; ▪ results of clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners; ▪ our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements; ▪ any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved; ▪ additions and departures of key personnel; ▪ strategic decisions by us or our competitors, such as acquisitions, divestitures, spin- offs, joint ventures, strategic investments or changes in business strategy; ▪ if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates; ▪ regulatory developments affecting our product candidates or those of our competitors; and ▪ changes in general market and economic conditions, including inflationary pressures. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or our amended and restated certificate of incorporation or our amended and amended and restated bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine ~~(~~**, or** the Delaware Forum Provision ~~)~~. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws will further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act ~~(~~**, or** the Federal Forum Provision ~~)~~. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are " facially valid " under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. If a court were to find either exclusive- forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business. Anti- takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and, therefore, decrease the trading price of our common stock. Our ~~fourth~~ **tenth** amended and restated

certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our **board of directors, or** Board **,** that our stockholders might consider favorable. Some of these provisions include: ▪ a Board divided into three classes serving staggered three- year terms, such that not all members of the Board will be elected at one time; ▪ a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; ▪ a requirement that special meetings of the stockholders may be called only by the Board acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, and special meetings of stockholders may not be called by any other person or persons; ▪ advance notice requirements for stockholder proposals and nominations for election to our Board; ▪ a requirement that no member of our Board may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds (2 / 3) of all outstanding shares of our voting stock then entitled to vote in the election of directors; ▪ a requirement of approval of not less than a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action and not less than two- thirds (2 / 3) of all outstanding shares of our voting stock to amend specific provisions of our certificate of incorporation; and ▪ the authority of the Board to issue preferred stock on terms determined by the Board without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These anti- takeover provisions and other provisions in our ~~fourth~~ **tenth** amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our Board or initiate actions that are opposed by the then- current Board and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our Board could cause the market price of our common stock to decline. Future sales and issuances of our common stock or rights to acquire shares of our common stock, could result in additional dilution to the ownership of our stockholders and cause the market price of our common stock to decline significantly. We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could be granted rights superior to our existing stockholders. In ~~November~~ **March** ~~2022~~ **2024** , we filed a registration statement on Form S- 3 relating to the registration of our common stock, preferred stock, debt securities, warrants and units or any combination thereof. Concurrently with the filing of such registration statement, we **filed** ~~engaged in~~ an " at- the- market " offering **prospectus supplement** ~~, or ATM~~ , which provides for the offering, issuance and sale by us of shares of our common stock from time to time for aggregate gross proceeds of up to $ 75 million in sales deemed to be " at- the- market offerings " as defined by the Securities Act. Any sale or issuance of securities pursuant to this registration statement or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline. Furthermore, new investors purchasing securities that we may issue and sell in the future could obtain rights superior to the rights of our existing stockholders. 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 of common stock intend to sell shares, could reduce the market price of our common stock. As of December 31, ~~2023~~ **2024** , we have 49, ~~350~~ **998** , ~~788~~ **279** shares of common stock outstanding. Significant portions of these shares are held by a small number of stockholders, including persons who were our stockholders prior to our ~~initial public offering, or~~ IPO. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, certain shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered or intend to register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. In addition, our directors, executive officers and certain affiliates may establish programmed selling plans under Rule 10b5- 1 of the Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline. General Risk Factors We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations. Among other matters, the U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We also expect our non- U. S. activities to increase in time. We plan to engage third parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Adverse developments

affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non- performance by financial institutions or transactional counterparties, could adversely affect ~~the~~ our company' s current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect our company, the financial institutions with which **we have** ~~our company has~~ credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which **we have** ~~our company has~~ financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: ▪ delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; ▪ loss of access to revolving existing credit facilities or other working capital sources and / or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; ▪ potential or actual breach of contractual obligations that require **us** ~~our company~~ to maintain letters ~~or~~ **of** credit or other credit support arrangements; ▪ potential or actual breach of financial covenants in our credit agreements or credit arrangements; ▪ potential or actual cross- defaults in other credit agreements, credit arrangements or operating or financing agreements; or ▪ termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on our company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to **us** ~~our company~~ and may **have** material adverse impacts on our business. Unfavorable global economic or..... and financial market conditions could adversely impact our business. Our employees, independent contractors, consultants, academic collaborators, partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, academic collaborators, partners and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to comply with the laws of the FDA, the EMA and comparable foreign regulatory authorities, provide true, complete and accurate information to the FDA, the EMA and comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain the FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors,

consultants, academic collaborators, partners and vendors, and the precautions we take to detect and prevent such activities 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. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations. We are an " emerging growth company " and a " smaller reporting company " and we cannot be certain if the reduced reporting requirements applicable to " emerging growth companies " and " smaller reporting companies " will make our common stock less attractive to investors. We are an " emerging growth company " as defined in the ~~Jumpstart Our Business Startups Act of 2012, or the~~ JOBS Act. For as long as we continue to be an " emerging growth company, " we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002 **, as amended,** or Section 404 ~~, as amended~~, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an " emerging growth company, " we are only required to provide two years of audited financial statements and two years of selected financial data in our periodic reports. We will remain an " emerging growth company " until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $ 1. 235 billion or (c) in which we are deemed to be a " large accelerated filer, " which requires the market value of our common stock that is held by non- affiliates to exceed $ 700. 0 million as of the prior June 30, and (ii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. Even after we no longer qualify as an " emerging growth company, " we may still qualify as a " smaller reporting company, " which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the independent auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile. Under the JOBS Act, " emerging growth companies " can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an " emerging growth company " or affirmatively and irrevocably opt out of the exemption provided by Section 7 (a) (2) (B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non- emerging growth companies and the date on which we will adopt the recently issued accounting standard. We are also a " smaller reporting company, " meaning that the market value of our stock held by non- affiliates is less than $ 700. 0 million and our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year. We may continue to be a " smaller reporting company " until (i) the market value of our stock held by non- affiliates is less than $ 250. 0 million or (ii) our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than $ 700. 0 million as of the prior June 30. If we are a " smaller reporting company " at the time we cease to be an " emerging growth company, " we may continue to rely on exemptions from certain disclosure requirements that are available to " smaller reporting companies. " Specifically, as a " smaller reporting company " we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K and, similar to emerging growth companies, " smaller reporting companies " have reduced disclosure obligations regarding executive compensation. The market price of our stock may be volatile, and you could lose all or part of your investment. The trading price of our common stock is highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, you may not be able to sell ~~their~~ **your** common stock at or above the price you paid for your common stock. The market price for our common stock may be influenced by many factors, including the other risks described in the section of this Annual Report ~~on Form 10- K~~ titled " Risk Factors " and the following: ▪ results of preclinical studies and results or enrollment of clinical trials of bel- sar or our future product candidates, or those of our potential future competitors or our existing or future collaborators; ▪ regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates; ▪ the success of future competitive products or technologies; ▪ introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements; ▪ actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing process or sales and marketing terms; ▪ actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us; ▪ the success of our efforts to acquire or in- license additional technologies, products or product candidates; ▪ developments concerning any future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners; ▪ market conditions in the pharmaceutical and biotechnology sectors; ▪ announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments; ▪ developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for bel- sar or our future product candidates and products; ▪ our ability or inability to raise additional capital and the terms on which we raise it; ▪ the recruitment or departure of

key personnel; ▪ changes in the structure of healthcare payment systems; ▪ actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally; ▪ our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; ▪ fluctuations in the valuation of companies perceived by investors to be comparable to us; ▪ announcement and expectation of additional financing efforts; ▪ speculation in the press or investment community; ▪ trading volume of our common stock; ▪ sales of our common stock by us or our stockholders; ▪ the concentrated ownership of our common stock; ▪ changes in accounting principles; ▪ natural disasters, pandemics and other calamities; ▪ acts of war or periods of widespread civil unrest, including the increasingly volatile global economic conditions resulting from the Russia- Ukraine conflict and **the** ~~Israel- Hamas~~ conflict **in the Middle East** ; and ▪ general economic, industry, and market conditions, including inflationary pressures. In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and adverse impact on the market price of our common stock. In the past, securities class action litigation has often been brought against public companies following declines in the market price of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result **in** ~~insubstantial~~ **substantial** costs and a diversion of management' s attention and our resources, which could harm our business. We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management devotes substantial time to compliance initiatives. As a public company, and particularly after we are no longer an " emerging growth company, " we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act and rules implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our products once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an " emerging growth company, " we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. In addition, for as long as we are a " smaller reporting company " with less than $ 100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404 (b) of the of the Sarbanes- Oxley Act of 2002. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In additional, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. However, any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Global economic uncertainty and unfavorable global economic conditions caused by political instability, changes in trade agreements and conflicts, such as the Russia- Ukraine ~~and Israel- Hamas conflicts~~ **conflict and the conflict in the Middle East** , could adversely affect our business, financial condition, results of operations or prospects. Our business, financial condition, results of operations or

prospects could be adversely affected by ~~general~~ **unstable economic and political** conditions **within the United States and foreign jurisdictions, including as a result of an economic downturn and geopolitical events, such as changes** in **U. S. federal policy that affect the geopolitical landscape. Changes to policy implemented by the U. S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among** ~~the~~ **other things, the U. S. and** global economy **, international trade relations, unemployment, immigration, healthcare, taxation, the U. S. regulatory environment, inflation** and ~~in the~~ **other areas. For example, during the prior Trump administration, increased tariffs were implemented on goods imported into the United States, particularly from China, Canada, and Mexico. On February 1, 2025, the United States imposed a 25 % tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10 % additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions, between not only the United States and China, but also between the United States and other countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U. S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of** global financial markets. ~~our business.Unfavorable global~~ **Any changes in political,trade,regulatory,and** economic ~~or political~~ conditions **,including U.S.trade policies,** could **have a material** ~~adversely~~ -- **adverse** ~~affect~~ **effect on** our ~~business,~~ financial condition or results of operations. ~~Our results~~ **Until we know what policy changes are made,whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business** of ~~operations could~~ **our competitors over the long term,we will not know if,overall,we will benefit from them or** be ~~adversely~~ **negatively** affected by ~~general conditions in the~~ **them** ~~global economy and in the global financial markets.For example,in 2008,the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and the COVID- 19 pandemic caused significant volatility and uncertainty in the U.S.and international markets~~ .In addition,the current military conflict between Russia and Ukraine and the armed conflict in Israel and the Gaza Strip could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely.Related sanctions,export controls or other actions that may be initiated by nations including the United States,the EU or Russia (e.g.,potential cyberattacks,disruption of energy flows,etc.),which could adversely affect our business and / or our supply chain,our CROs,CDMOs and other third parties with which we conduct business. ~~A severe or prolonged economic downturn or political unrest could~~ A severe or prolonged economic downturn **or** ~~, increased inflation, economic uncertainties in various global markets caused by~~ political **unrest** ~~instability and conflict, such as the Russia- Ukraine and Israel- Hamas conflicts, or additional global financial crises,~~ could result in a variety of risks to our business, including **but not limited to** weakened demand for our product candidates **and** ~~, if approved, or our~~ ~~our inability~~ -- **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 services** . Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current **political and** economic climate and financial market conditions could adversely impact our business. ~~83~~ **89**