Risk Factors Comparison 2024-03-28 to 2023-03-16 Form: 10-K

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You should carefully consider the risks and uncertainties described below, together with all of the other information in this ~~annual~~ **Annual** ~~report~~ **Report** on Form 10- K. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This ~~annual~~ **Annual** ~~report~~ **Report** on Form 10- K also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward- looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this ~~annual~~ **Annual** ~~report~~ **Report** on Form 10- K. Risks Related to Our Financial Position and Capital Needs We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities, have not generated any product revenues to date, and have incurred significant research, development and other expenses related to our ongoing operations. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, we reported a net loss of $ ~~41~~ **37**. 3 million and $ ~~20~~ **41**. ~~7~~ **3** million, respectively. As of December 31, **2023 and** 2022 ~~and 2021~~, we had an accumulated deficit of $ **217. 2 million and $** 179. 9 ~~million and $ 138. 6~~ million, respectively. We do not expect to generate product revenues for many years, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidates and any additional product candidates we may acquire, and potentially begin to commercialize product candidates that may achieve regulatory approval. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our expenses will further increase as we: • conduct additional clinical trials of our lead product, GPS, including the Phase 3 clinical trial evaluating GPS for AML, and our second clinical candidate, **SLS009** ~~GFH009; • hire additional personnel, including clinical, manufacturing, quality control, quality assurance and other scientific personnel, sales and marketing personnel and general and administrative personnel~~; • seek marketing approval for any of our product candidates that successfully complete clinical trials; • develop our outsourced manufacturing activities and establish sales, marketing and distribution capabilities, if we receive, or expect to receive, marketing approval for any product candidates; • in- license or acquire the rights to, and pursue development of, other products, product candidates or technologies; • maintain, expand and protect our intellectual property portfolio; **• hire additional personnel, including clinical, manufacturing, quality control, quality assurance and other scientific personnel, sales and marketing personnel and general and administrative personnel;** and • add operational, financial and management information systems and personnel. We currently have no source of revenues from product sales. We may never generate such revenues or achieve profitability. Currently, we do not generate any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when we will generate revenues or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including our current product candidates, and other product candidates that we may develop, in- license or acquire in the future. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to: • successfully complete development activities, including the necessary clinical trials; • complete and submit BLAs and NDAs to the FDA and obtain U. S. regulatory approval for indications for which there is a commercial market; • complete and submit applications to foreign regulatory authorities in Europe, Asia and other jurisdictions; • obtain regulatory approval in territories with viable market sizes; • obtain coverage and adequate reimbursement from third parties, including government and private payors; • set commercially viable prices for our products, if any; • establish and maintain supply and manufacturing relationships with reliable third parties and / or build our own manufacturing facility and ensure adequate, legally globally compliant manufacturing of bulk drug substances and drug products to maintain that supply; • develop distribution processes for our product candidates; • develop commercial quantities of our product candidates, once approved, at acceptable cost levels; • obtain additional funding, if required to develop and commercialize our product candidates; • develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves, in the markets in which we choose **to commercialize on our own, and successfully enter into arrangements with third parties to sell, market, and distribute our products in markets where we choose not** to commercialize on our own; • achieve market acceptance of our products; • attract, hire and retain qualified personnel; and • protect our rights in our intellectual property portfolio. Our revenues for any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which it gains regulatory 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 disease patients is not as significant as our estimates, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenues from sales of such products,

even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations. We will need additional financing to fund our operations and complete the development and, if approved, the commercialization of our product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts. We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of GPS, in particular the Phase 3 study of GPS in AML, and ~~GFH009~~ **SLS009** . Our existing cash will not be sufficient to complete such development activities and obtain regulatory approval for our product candidates and, if we receive regulatory approval for our product candidates, commence commercialization activities, and we will need to raise significant additional capital to help us do so. In addition, our operating plan may change as a result of factors currently unknown to us, and we may need additional funds sooner than planned. If we are unable to obtain sufficient funding for our operations, we may be delayed in pursuing our development programs for GPS and ~~GFH009~~ **SLS009** . Our future capital requirements depend on many factors, including: • the scope, progress, results and costs of our ongoing and planned development programs for our product candidates, as well as any additional clinical trials we undertake to obtain data sufficient to seek marketing approval for our product candidates in any indication; • the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if our clinical trials are successful; • the cost of commercialization activities for our product candidates, if any of these product candidates are approved for sale, including marketing, sales and distribution costs; • the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval, including the cost and timing of process development, manufacturing scale- up and validation activities; • our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements; • the costs to in- license future product candidates or technologies; • the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; • the costs in defending and resolving future derivative and securities class action litigation; • our operating expenses; and • the emergence of competing technologies or other adverse market developments. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. ~~We have no committed source of additional capital other than our ATM facility.~~ Moreover, global and domestic events, such as public health crises, geopolitical unrest and domestic political events, have caused and could continue to cause uncertainty and volatility in the capital markets which could impact our ability to raise capital. If adequate funds are not available to us on a timely basis, we may not be able to continue as a going concern or we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or target indications, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us. We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under management or other types of contracts, or upon the exercise or conversion of outstanding derivative securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti- dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in the event of a liquidation. In such event, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of our common stock. Debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets, including our intellectual property, and for our subsidiaries to guarantee our obligations. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, products or product candidates or grant licenses on terms that may not be favorable to us. Our cash and cash equivalents balance as of December 31, ~~2022~~ **2023** will fund our operations for less than one year. As of December 31, ~~2022~~ **2023** , we had a cash and cash equivalents balance of approximately $ ~~17~~ **2** . ~~1~~ **5** million. We expect our existing cash and cash equivalents balance as of December 31, ~~2022~~ **2023** , will be insufficient to fund current planned operations for at least the next ~~twelve~~ **12** months from the date of issuance of our consolidated financial statements for the year ended December 31, ~~2022~~ **2023** , and that we will need to raise additional capital in order to continue our operations as currently planned. In the event that we are unable to obtain additional financing, we may be unable to continue as a going concern. There is no guarantee that we will be able to secure additional financing. Changes in our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our development activities, any near- term or future expansion plans, increased expenses, potential acquisitions or other events may further affect our ability to continue as a going concern. See Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10- K for additional information on our assessment. Similarly, the report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, ~~2022~~ **2023** includes an Emphasis of Matter paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we cannot continue as a viable entity, our security holders may lose some or all of their

investment in us. 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 our 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. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. **If any** ~~Although a statement by the Department~~ of **our counterparties** ~~the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access~~ to **any** ~~all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under~~ credit agreements, letters of credit ~~and~~ **or** certain other financial ~~instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our counterparties to any such~~ instruments that we may enter into in the future were to be placed into receivership, we may be unable to access such funds. In addition, if any parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected ~~. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry~~ . Similar impacts have occurred in the past, such as during the 2008- 2010 financial crisis. 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 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 us, the financial institutions with which we have 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 financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. 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 parties with whom we conduct business, 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 party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. Risks Related to the Development and Regulatory Approval of Our Product Candidates Clinical- stage biopharmaceutical companies with product candidates in clinical development face a wide range of challenging activities which may entail substantial risk. The success of our product candidates will depend on several factors, including the following: • designing, conducting and successfully completing preclinical development activities, including preclinical efficacy and IND- enabling studies, for our product candidates or product candidates we are interested in in- licensing or acquiring; • designing, conducting and completing clinical trials for our product candidates with positive results; • receipt of regulatory approvals from applicable authorities; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; • making arrangements with third- party manufacturers, receiving regulatory approval of our manufacturing processes and our third- party manufacturers' facilities from applicable regulatory authorities and ensuring adequate supply of drug product; • manufacturing our product candidates at an acceptable cost; • effectively launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others; • achieving acceptance of our product candidates, if approved, by patients, the medical community and third- party payors; • effectively competing with other therapies; • if our products candidates are approved, obtaining and maintaining coverage and adequate reimbursement by

third- party payors, including government payors, for our product candidates; • complying with all applicable regulatory requirements, including FDA ~~current Good Clinical Practices, or cGCP~~ **GCP and** ~~, current Good Manufacturing Practices, or~~ cGMP **requirements** , ~~and~~ **as well as,** standards, rules and regulations governing promotional and other marketing activities; • maintaining a continued acceptable safety profile of the products during development and following approval; and • maintaining and growing an organization of scientists and **businesspeople** ~~business people~~ who can develop and commercialize our product candidates. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which could materially harm our business. Our lead product candidate, GPS, represents a new therapeutic approach that presents significant challenges. Our future success is substantially dependent on the successful development of WT1 peptide immunotherapies in general and GPS in particular. Because this program represents a new approach to cancer immunotherapy for the treatment of cancer and other diseases, developing and commercializing GPS subjects us to a number of challenges, including: • obtaining regulatory approval from the FDA and other regulatory authorities, which have very limited experience with the development and commercialization of WT1 cancer immunotherapies; • obtaining the components required for the administration of GPS (i. e., GPS, GM- CSF, and Montanide) from three separate sources, the subsequent separate storage requirements for each of these components and the separate delivery of these components to the administration location; • utilizing GPS in combination with other therapies, which may increase the risk of adverse side effects; • sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process GPS; • developing a manufacturing process used in connection with GPS that will yield a satisfactory product that is safe, effective, scalable and profitable; • establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance; and • obtaining coverage and adequate reimbursement from third- party payors and government authorities. Moreover, public perception of safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment mechanics. Physicians, hospitals and third- party payors often are slow to adopt new products, technologies and treatment practices that require additional educational upfront costs and training. Physicians may not be willing to undergo training to adopt this novel therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh their costs. The limited number of patients who have the diseases for which our product candidates are being studied, has made it more difficult to enroll patients in our clinical trials, which could delay or prevent the start of clinical trials for our product candidates. Identifying and qualifying patients to participate in clinical trials of our current and future product candidates is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. If we experience delays in our clinical trials, the timeline for obtaining regulatory approval of our product candidates will most likely be delayed. Many factors may affect our ability to identify, enroll and maintain qualified patients, including the following: • shortages of personnel at our clinical sites; • eligibility criteria of our ongoing and planned clinical trials with specific characteristics appropriate for inclusion in our clinical trials; • design of the clinical trial; • size and nature of the patient population; • patients' perceptions as to risks and benefits of the product candidate under study and the participation in a clinical trial generally in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; • the availability and efficacy of competing therapies and clinical trials; • pendency of other trials underway in the same patient population; • willingness of physicians to participate in our planned clinical trials; • severity of the disease under investigation; • proximity of patients to clinical sites; • patients who do not complete the trials for personal reasons; and • issues with contract research organizations, or CROs, and / or with other vendors that handle our clinical trials. The indication being studied in our Phase 3 clinical trial for GPS, i. e., patients with AML who have achieved CR2, is an orphan indication. In addition, only those CR2 patients who meet specific inclusion criteria are eligible to participate in the study. Primary entry restrictions include demonstrating adequate hematologic recovery ~~,~~ **and** not being candidates for bone marrow transplants ~~and not being eligible for treatments targeted at certain mutations common in significant proportions of AML patients~~ . The estimated prevalence of newly diagnosed AML patients is approximately 20, 000 cases in the United States annually (across all ages) with only a subset of this group having achieved CR2 and only a further subset of the CR2 subset satisfying the enrollment criteria for our AML Phase 3 clinical trial. We may not be able to initiate or continue to support clinical trials of our product candidates for one or more indications, or any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete **. Congress also recently amended the FDCA to require sponsors of a Phase 3 clinical trial, or other " pivotal study " of a new drug or biologic to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Our Phase 3 REGAL trial of GPS for AML patients who have achieved CR2 was initiated before this requirement became effective, but for any future Phase 3 trials we plan to conduct, including any registrational study for SLS009, we must submit a diversity action plan to the FDA by the time we submit plans for such Phase 3, or pivotal study, protocol to the agency for review as part of an IND, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase 3 trial for our product candidates or what specific information FDA will expect in such plans. However, initiation of such trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase 3 trial for our product candidates, and we may experience difficulties recruiting a**

diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan . If we experience delays in the completion of, or termination of, any clinical trials of our current or future product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly. The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidates in clinical trials, and any other product candidates that may advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. Any of our product candidates that are in, or may advance to, clinical trials may not succeed in clinical trials despite promising preclinical data. For example, with respect to GPS, a broadly similar anti- cancer peptide immunotherapeutic against melanoma- specific antigen being developed by GlaxoSmithKline for advanced unresectable melanoma initially produced positive efficacy data in a Phase 2 clinical study, but subsequently failed to prove more beneficial than placebo in a controlled, blinded and randomized Phase 3, registration- enabling clinical trial in the same indication in patients after tumor resection. Despite the results reported in earlier preclinical studies or clinical trials for our product candidates, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates for a particular indication, either as a monotherapy or in combination, in any particular jurisdiction. Efficacy data from prospectively designed trials may differ significantly from those obtained from retrospective subgroup analyses. If later- stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our current or future product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials. Interim, topline and preliminary 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, interim or topline 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 a 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 evaluate all data. As a result, the topline results or preliminary data 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. Topline 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, topline 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 complete are subject to the risk that one or more of the clinical outcomes may materially change as more patient data becomes available. Adverse changes between interim data and final data could adversely affect our business and prospects and could result in volatility in the price of our common stock. We **are developing and** may **continue to** develop our programs in combination with other therapies, which exposes us to additional risks. We **are currently investigating SLS009 in combination with aza / ven in a Phase 2a clinical trial and we** may **continue to** develop ~~our~~ clinical candidates in combination with one or more currently approved cancer therapies or therapies currently in clinical development. Patients may not be able to tolerate our product candidates in combination with other therapies or dosing of our product candidates in combination with other therapies may have unexpected consequences. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or ~~safely~~ **safety** , efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being less successful commercially. We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or successfully market our product candidates. Additionally, if the third- party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse impact on our business, financial condition, results of operations and growth prospects. Clinical drug development involves a lengthy and expensive process with an uncertain outcome. Clinical testing is expensive and can take many years to complete, with the outcome inherently uncertain. Failure can occur at any time during the clinical trial process. Before obtaining approval from regulatory authorities for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Prior to initiating clinical trials, a sponsor must complete extensive preclinical testing of a product candidate, including,

in most cases, preclinical efficacy experiments as well IND- enabling toxicology studies. These experiments and studies may be time- consuming and expensive to complete. The necessary preclinical testing may not be completed successfully for a preclinical product candidate and a potentially promising product candidate may therefore never be tested in humans. Once it commences, clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous unforeseen events during drug development that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. In particular, clinical trials of our product candidates may produce inconclusive or negative results. We have limited data regarding the safety, tolerability and efficacy of GPS administered as monotherapy or in combination with PD- 1 inhibitors or for ~~GFH009~~ **SLS009** as monotherapy and ~~no safety, tolerability or efficacy data for GFH009 administered~~ in combination with other therapeutics, ~~such as venetoclax~~ **including aza / ven** . For a further discussion of the safety risks in our trials, see the risk factor herein entitled" Our current and future product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval." Clinical trials also require the review and oversight of an IRB. An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical trials, and the FDA may decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval. We may experience delays in our ongoing or future clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA will not put clinical trials of any of our product candidates on clinical hold in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as: • delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a clinical trial design that we are able to execute; • delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial; • delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site; • withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials; • ~~the impact of COVID- 19 on the operations of clinical sites; •~~ clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial; • inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication; • failure of our third- party clinical trial managers, CROs, clinical trial sites, contracted laboratories or other third- party vendors to satisfy their contractual duties, meet expected deadlines or return trustworthy data; • delay or failure in adding new trial sites; • delay or failure in recruiting and enrolling suitable subjects to participate in a trial; • delay or failure in subjects completing a trial or returning for post- treatment follow- up; • interim results or data that are ambiguous or negative or are inconsistent with earlier results or data; • alteration of trial design necessitated by re- evaluation of design assumptions based upon observed data; • feedback from the FDA, ~~the IRB, DSMB~~ or ~~a comparable~~ foreign regulatory authority **, the IRB, or DSMB** , or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial; • a decision by the FDA **or** ~~, the IRB, a comparable~~ foreign regulatory authority **, the IRB** , or us, or a recommendation by a DSMB or comparable foreign regulatory authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason; • unacceptable risk- benefit profile, unforeseen safety issues or adverse side effects; • failure to demonstrate a benefit from using a product candidate; • difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate to start or to use in clinical trials; • lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or • changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical trial. If we experience delays in the completion or termination of any clinical trial of our product candidates, the approval and commercial prospects of such product candidates will be harmed, delaying our ability to generate product revenues from such product candidate and our costs will most likely increase. The required regulatory approvals may also be delayed, thereby jeopardizing our ability to commence product sales and generate revenues and the period of commercial exclusivity for our products may be decreased. Regulatory approval of our product candidates may be denied for the same reasons that caused the delay. Risks associated with operating in foreign countries could materially adversely affect our product development. For certain of our clinical trials, we have clinical sites in countries outside of the United States. Consequently, we may be subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include: • differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries; more stringent privacy requirements for data to be supplied to our operations in the United States, e. g., GDPR ~~the~~ in the **EU** ~~European Union~~ ; • unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign taxes, including withholding of payroll taxes; • differing payor reimbursement regimes, governmental payors or patient self- pay systems and price controls; • foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or

operating in another country; • workforce uncertainty in countries where labor unrest is more common than in the United States; • continued uncertainties related to the withdrawal of the United Kingdom from the **EU** ~~European Union~~ (known as" Brexit") and its financial, trade, regulatory and legal implications, which could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which EU laws to replace or replicate, and which may further create global economic uncertainty, which could materially adversely affect our business, business opportunities, results of operations, financial condition, and cash flows; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad, including those that may result from the recent coronavirus outbreak; and • business interruptions resulting from geopolitical actions, including war and terrorism. Global, market and economic conditions may negatively impact our business, financial condition and share price. The results of our operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The United States and global economies ~~are facing~~ **have recently faced** growing inflation, higher interest rates and a potential recession. Furthermore, a ~~severe or~~ prolonged economic downturn, including a recession or depression resulting from ~~the~~ **public health crises such as a pandemic or** ongoing ~~COVID- 19 pandemic or~~ political disruption such as the war between Ukraine and Russia **and the conflict involving Israel and Hamas** could result in a variety of risks to our business, including weakened demand for our programs and development candidates, if approved, relationships with any vendors or business partners located in affected geographies and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, **particularly between the United States and China,** could also strain our **existing or future partnerships,** manufacturers or suppliers, possibly resulting in **disruption to our clinical trials or** supply ~~disruption~~, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business. Although we do not currently have any clinical study sites in Russia or Ukraine, economic, political and social conditions resulting from Russia' s invasion of Ukraine could materially disrupt our clinical trials, increase our costs and may disrupt planned clinical development activities. For example, we currently have clinical sites for our REGAL study in Poland, a country that borders Ukraine and has been impacted by an influx of Ukrainian refugees resulting from Russia' s invasion of Ukraine. Furthermore, we rely on suppliers in the EU. To the extent the conflict between Ukraine and Russia adversely impacts the ability of our suppliers to distribute the supplies we need for our clinical trials, or such distribution cannot be done on a timely basis, the timing for completing our clinical trials may be adversely impacted. **Continued increases in inflation could raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows. In response to high levels of inflation and recession fears, the U. S. Federal Reserve, the European Central Bank, and the Bank of England have raised, and may continue to raise, interest rates and implement fiscal policy interventions. Even if these interventions lower inflation, they may also reduce economic growth rates, create a recession, and have other similar effects. The U. S. debt ceiling and budget deficit concerns have increased the possibility of credit- rating downgrades and economic slowdowns, or a recession in the United States. Although U. S. lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, there is a history of ratings agencies lowering or threatening to lower the long- term sovereign credit rating on the United States given such uncertainty. On August 1, 2023, Fitch Ratings downgraded the United States' long- term foreign currency issuer default rating to AA from AAA as a result of these repeated debt ceiling and budget deficit concerns. The impact of this or any further downgrades to the U. S. government' s sovereign credit rating or its perceived creditworthiness could adversely affect the U. S. and global financial markets and economic conditions. If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult to secure, more costly or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could harm our growth strategy, financial performance and stock price and could require us to delay or abandon plans with respect to our business, including clinical development plans. Further, recent developments in the banking industry could adversely affect our business. If the financial institutions with which we do business enter receivership or become insolvent in the future, there is no guarantee that the Department of the Treasury, the Federal Reserve and the FDIC will intercede to provide us and other depositors with access to balances in excess of the $ 250, 000 FDIC insurance limit, that we would be able to access our existing cash, cash equivalents and investments, that we would be able to maintain any required letters of credit or other credit support arrangements, or that we would be able to adequately fund our business for a prolonged period of time or at all, any of which could have a material adverse effect on our business, financial condition and results of operations. We cannot predict the impact that the high market volatility and instability of the banking sector more broadly could have on economic activity and our business in particular. In addition, there is a risk that one or more of our current service providers, manufacturers or other third parties with which we conduct business may not survive difficult economic times, the ongoing conflict between Russia and Ukraine, the war between Israel and Hamas, the instability of the banking sector, and the uncertainty associated with current worldwide economic conditions, which could directly affect our ability to attain our operating goals on schedule and on budget. Our partnerships in China subject us to risks and uncertainties relating to the laws and regulations of China and the changes in relations between the United States and China. Under its current leadership, the government of China has been pursuing economic reform policies, including by encouraging foreign trade and investment. However, there is no assurance that the Chinese government will continue to pursue such policies, that such**

policies will be successfully implemented, that such policies will not be significantly altered, or that such policies will be beneficial to our partnerships in China. China' s system of laws can be unpredictable, especially with respect to foreign investment and foreign trade. The U. S. government has called for substantial changes to foreign trade policy with China and has raised, and has proposed to further raise in the future, tariffs on several Chinese goods. China has retaliated with increased tariffs on U. S. goods. Moreover, China' s legislature has adopted a national security law to substantially change the way Hong Kong has been governed since the territory was handed over by the United Kingdom to China in 1997. This law increases the power of the central government in Beijing over Hong Kong, limit the civil liberties of residents of Hong Kong and could restrict the ability of businesses in Hong Kong to continue to conduct business or to continue to with business as previously conducted. The U. S. State Department has indicated that the United States no longer considers Hong Kong to have significant autonomy from China. The U. S. State Department also previously enacted sanctions related to China' s governing of Hong Kong, and the United States may impose the same tariffs and other trade restrictions on exports from Hong Kong that it places on goods from mainland China. Any further changes in U. S. trade policy could trigger retaliatory actions by affected countries, including China, resulting in trade wars. For example, the Uyghur Forced Labor Prevention Act bans imports from China' s Xinjiang Uyghur Autonomous Region unless it can be shown that the goods were not produced using forced labor and this legislation may have an adverse effect on global supply chains which could adversely impact our business and results of operations. Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are also unpredictable. Any regulatory changes and changes in United States and China relations may have a material adverse effect on our partnerships in China which could materially harm our business and financial condition. Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects. Climate change may potentially negatively affect our business and results of operations, cash flows and prospects in the future. We could be exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low- carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk), and social and human effects (such as population dislocations and harm to health and well- being) associated with climate change. These risks can be either acute (short- term) or chronic (long- term). Extreme weather and sea- level rise could pose physical risks to facilities of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events which could disrupt our operations and supply chains that may result in increased costs. New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us. Our current and future product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval. Undesirable side effects caused by our current or future product candidates, their delivery methods or dosage levels could cause us **, the IRB, DSMB,** or **the FDA or comparable** 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 or termination of clinical trials ~~by the FDA or other comparable foreign regulatory authority; an independent DSMB that is governing our clinical trials; or an IRB, that approves and, monitors biomedical research to protect the rights and welfare of human subjects~~ . For example, although no high- grade delayed type hypersensitivity in the skin or systemic anaphylaxis events have been noted after GPS administration in patients treated in our clinical studies to date, it is theoretically possible that such toxicities, or other type of adverse events, may occur in future clinical studies. As a result of safety or toxicity issues that we may experience in our clinical trials, or negative or inconclusive results from the clinical trials of others for drug candidates similar to our own, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug- related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects. Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that: • we may be forced to suspend marketing of such product; • regulatory authorities may withdraw their approvals of such product; • regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such ~~products~~ **product** ; • we may be required to conduct post- marketing studies; • we may be required to change or the health care setting in which the way the product is administered; • we could be sued and held liable for harm caused to subjects or patients; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved. Our product development program may not uncover all possible adverse events that patients who take our product candidates may experience. The number of subjects exposed to product candidates and the average exposure time in the clinical development

program may be inadequate to detect rare adverse events or chance findings that may only be detected once the product is administered to more patients and for greater periods of time. Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, we cannot be fully assured that rare and severe side effects of our product candidates will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients exposed to our product candidates. If such safety problems occur or are identified after **any of** our product candidates reaches the market, the FDA may require that we amend the labeling of the product or recall the product, or may even withdraw approval for the product, any of which could subject us to substantial product liability claims and related litigation. Our future success is dependent on the regulatory approval of our product candidates. Our business is dependent on our ability to obtain regulatory approval for our product candidates in a timely manner. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered ~~in~~ **from** preclinical studies and ~~clinical trials, generally including~~ well- controlled **clinical** ~~Phase 3~~ trials ~~,~~ that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion and available resources of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn. Our current and future product candidates could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities. We have not obtained regulatory approval for any product candidate and it is possible that our existing product candidates or any future product candidates will not obtain regulatory approval, for many reasons, including: • disagreement with the regulatory authorities regarding the scope, design or implementation of our clinical trials; • failure to demonstrate that a product candidate is safe and effective for our proposed indication; • failure of clinical trials to meet the level of statistical significance required for approval; • failure to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • disagreement with our interpretation of data from preclinical studies or clinical trials; • the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA, NDA or other submission or to obtain regulatory approval; • the insufficiency of a single Phase 3 clinical trial of GPS in AML for regulatory approval in that indication; • failure to obtain approval of our manufacturing processes or facilities of third- party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or • changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval or additional studies, **to support a marketing approval decision,** which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), 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. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate. We currently have **ODD** ~~Orphan Drug Product~~ designation for GPS **and SLS009** for certain ~~indications, and may seek Orphan Drug Product designation for additional product candidates, including GFH009, or~~ indications, which might not ~~be received or~~ provide the intended benefit thereof. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as Orphan Drug Products. Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug Product if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States. We have received **ODD** ~~Orphan Drug Product designations~~ from the FDA for GPS in AML, MPM and MM as well as Orphan Medicinal Product designations from the EMA for GPS in AML, MPM and MM. ~~Although~~ **In addition,** we have received ~~Orphan Drug Product designation~~ **ODD from the FDA for SLS009 for the treatment of AML and PTCL. Although we have received ODD** for GPS **and SLS009** , there is no guarantee that any of these indications for GPS **or SLS009** will be successfully approved by the FDA or the EMA, that GPS **or SLS009** will be commercially successful in the marketplace, or that another product will not be approved for the same indication ahead of our product candidate. Even if we obtain ~~Orphan~~ **orphan** ~~Drug Product~~ **product** exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same **disease or** condition. Even after an Orphan Drug Product is approved, the FDA can subsequently approve another drug **or biologic** for the same **disease or** condition if the FDA concludes that the later ~~drug~~ **product** is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, Orphan ~~Drug Product~~ **product** exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. We currently have Fast Track designation for GPS and **SLS009 and** may seek Fast Track designation for additional product

candidates ~~, including GFH009~~, or indications, which might not be received or provide the intended benefits thereof. If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply to the FDA for Fast Track designation, which may or may not be granted by the FDA. We have received Fast Track designation from the FDA for GPS in AML, MPM and MM **and Fast Track designation for SLS009 for the treatment of r / r AML and r / r PTCL** . However, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA' s **accelerated approval or** priority review procedures. Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad. In addition to regulations in the United States, to market and sell our product candidates in the **EU** ~~European Union~~, United Kingdom, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. The approval ~~procedure~~ **procedures** ~~varies~~ **vary** among countries and can involve additional **nonclinical or clinical** testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. We may not be able to obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country, or may receive reimbursement at a level that is not commercially viable. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our current or future product candidates by regulatory authorities in the **EU** ~~European Union~~, United Kingdom, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished, our business prospects could decline and this could materially adversely affect our business, results of operations and financial condition. Even if our current and future product candidates receive regulatory approval, they may still face future development and regulatory difficulties. Any regulatory approvals we receive for any of our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials. In addition ~~. Any~~ **, any** such regulatory approvals would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance by us and / or our ~~contract~~ **CMOs with respect to product quality and** manufacturing ~~organizations,~~ **operations and** ~~or~~ **our** ~~CMOs, and~~ CROs for any post- approval clinical trials that we may conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a **REMS** ~~risk evaluation and mitigation strategy~~, impose significant restrictions on a product' s indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post- marketing clinical trial to confirm the clinical benefit for our products. An unsuccessful post- marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval. In addition, manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring quality control and manufacturing procedures conform to cGMP, regulations and corresponding foreign regulatory manufacturing requirements. Accordingly, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or NDA submission to the FDA or any other type of domestic or foreign marketing authorization application. We or our third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If any of our third- party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our product candidates could suffer significant interruptions. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may take the following actions, any of which could significantly and adversely affect supplies of our products: • issue Form 483 notices of observations, warning letters or untitled letters; • mandate modifications to promotional materials or require us to provide corrective information to health care practitioners; • require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due

dates for specific actions and penalties for noncompliance; • seek an injunction or impose civil or criminal penalties or monetary fines; • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve pending applications or supplements to applications filed by us; • suspend or impose restrictions on operations, including costly new manufacturing requirements; or • seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall. Any government investigation of alleged violations of law would require us to expend significant time and resources in response and could generate adverse publicity. The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products and generate revenues. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the DOJ, the Office of Inspector General ~~of the U. S. Department of Health and Human Services, or~~ **for the** ~~HHS~~ **DHHS**, state attorneys general, members of Congress and the public. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities. Violations, including actual or alleged promotion of our products for unapproved or off- label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA, as well as **potential** prosecution under the federal False Claims Act. Any actual or alleged failure to comply with labeling and promotion requirements may have a negative impact on our business. Risks Related to Our Manufacturing We have limited to no manufacturing or distribution capability and must rely upon third parties for such. We currently have direct or indirect agreements or arrangements with various third- party manufacturing facilities for production of our product candidates for research and development and testing purposes. For example, for ~~GFH009~~ **SLS009** we are party to a supply agreement with GenFleet who has agreements with third-party manufacturers for the manufacture of ~~GFH009~~ **SLS009**. We depend on these manufacturers to meet our deadlines, quality standards and specifications. Reliance on third- party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the manufacturing processes of the CMOs we rely on and are dependent on those third parties for the production of our product candidates in accordance with relevant applicable regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Our reliance on third parties for the manufacture of our active pharmaceutical ~~ingredient~~ **ingredients** and **investigational** drug ~~product~~ **products** and, in the future, any approved products, creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If the contracted manufacturing source is unreliable or unavailable, we may not be able to manufacture clinical ~~drug~~ supplies of our product candidates, and our preclinical and clinical testing programs may not be able to move forward and our entire business plan could fail. The third- party manufacturers we rely on for **the** manufacture of our product candidates are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter are subject to ongoing inspection from time to time. Our third- party manufacturers may not be able to comply with **applicable** cGMP regulations or similar regulatory requirements outside of the United States. In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third- party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record- keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. If either we or the CMOs we rely on fail to comply with these requirements, our ability to develop and commercialize our product candidates could suffer significant interruptions, and we may be subject to regulatory enforcement action, including the seizure of products and shutting down of production. Both the active pharmaceutical ingredient and drug product for our product candidates are currently single **-** sourced. We believe these single sources are currently capable of supplying all anticipated needs of our proposed clinical studies, as well as initial commercial introduction **should such product candidates received regulatory approval**. If we are able to commercialize our products in the future, there is no assurance that our manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or cGMP. Once the nature and scope of additional indications and their commensurate drug product demands are established, we will seek secondary suppliers of both the active pharmaceutical ~~ingredient~~ **ingredients** and drug ~~product~~ **products** for our product candidates, but we cannot assure that such secondary suppliers will be found on terms acceptable to us, or in a timely manner, or at all. We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates. We and the CMOs we rely on will need to conduct significant development work for each product candidate for each target indication for studies, trials and commercial launch readiness. We intend to improve the existing processes for GPS in connection with more advanced clinical trials or commercialization efforts we may undertake in the future. Developing commercially viable manufacturing processes is a difficult, expensive and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with process scale- up, process reproducibility, stability issues, storage issues, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product candidates will be made could be adversely affected by the recent coronavirus outbreak, other pandemics, earthquakes and other natural disasters, equipment failures, labor shortages, lack of adequate temperature controls, power failures, and numerous other factors. We currently estimate that we have sufficient clinical supplies to support our clinical trials ~~for at least the next 12 months~~, however, this estimate is dependent on patient enrollment rates and a number of other factors and, accordingly, could change. Moreover, current clinical supplies may not be adequate for future clinical studies. Additionally, the process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including but not limited to: • product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error; • product loss or manufacturing failure due to failure of temperature controls in production, storage or transit; • product loss, which may not be covered by insurance, due to global conflict and unrest, including related inoperability of

shipping lanes; • reduced production yields, product defects, and other supply disruptions due to deviations, even minor, from normal manufacturing and distribution processes; • **inability to procure or delay in procuring raw materials and reagents for manufacturing products; •** unexpected product defects; • microbial, viral, or other contaminations in our product candidates or in the manufacturing facilities in which our product candidates are made, which may result in the closure of such manufacturing facilities for an extended period of time to allow for the investigation and remediation of the contamination; • adverse impact on the active ingredient of GPS as a result of potential contamination from the presence of heavy metals which can lead to higher than acceptable rates of impurities resulting in the active ingredient being unacceptable for use; and • adverse impact on the manufacturing of GPS as a result of potential contamination from excess ~~water~~ **humidity** and oxygen which can lead to higher than acceptable levels of impurities resulting in the drug product being unacceptable for use. Any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug substance and drug product, which could delay the development of our product candidates. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our product candidates could damage our reputation and the reputation of our products among physicians, health care payors, patients or the medical community, and cancer treatment centers, which could adversely affect our ability to operate our business and our results of operations. In ~~the~~ **our GPS** clinical trials ~~using GPS~~, GM-CSF ~~,~~ and Montanide are also administered **in addition to GPS** and their availability is dependent upon third- party manufacturers, which may or may not reliably provide GM- CSF or Montanide, thus jeopardizing the completion of the trials. GPS is administered in combination with GM- CSF, which is available ~~in both liquid and lyophilized forms~~ exclusively from one manufacturer **, and Montanide, which is exclusively available from another supplier**. We will continue to be dependent on ~~that~~ **these** ~~manufacturer~~ **manufacturers** for our supply of **these materials** ~~GM- CSF~~ in connection with the ongoing GPS trials and the potential commercial manufacture of GPS. We have not entered into a dedicated supply agreement with the ~~manufacturer~~ **manufacturers** for GM- CSF **or Montanide**, and instead rely on purchase orders to meet our supply needs. Any temporary interruptions or discontinuation of the availability of **these materials** ~~GM- CSF~~, or any determination by us to change ~~the~~ **their** ~~GM- CSF used~~ **use** with GPS, could have a material adverse effect on our clinical trials and any commercialization of the assets ~~. Similarly, for GPS, Montanide is also administered in combination with GM- CSF and GPS. Any temporary interruptions or discontinuation of the availability of Montanide could have a material adverse effect on our clinical trials for GPS and any commercialization of the asset~~. If any of the clinical manufacturing facilities of CMOs we rely on for clinical supply are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected. If the manufacturing facilities of the CMOs we rely on for clinical supply or the equipment in them is damaged or destroyed, we may not be able, quickly or inexpensively, to replace such manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of a facility or equipment, we might not be able to transfer manufacturing to another CMO. Even if we could transfer manufacturing to another CMO, the shift would likely be expensive and time- consuming, particularly because the new facility would need to comply with the necessary regulatory requirements, and we would need FDA approval before selling any products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales. Although we currently maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. In addition, our clinical trials insurance coverage has exclusions for global conflict and unrest ~~or~~ **of** the type currently ongoing in Ukraine. We may be unable to meet our requirements for our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes. Risks Related to Our Dependence on Third Parties and Our License Agreements We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if we lose any of our CROs or other key third- party vendors, we may not be able to obtain regulatory approval for or commercialize our current or future product candidates on a timely basis, if at all. Our internal capacity for clinical trial execution and management is limited and therefore we rely heavily on third parties. We have relied upon and plan to continue to rely upon third- party CROs, vendors and contractors to monitor and manage data for our ongoing preclinical and clinical programs. We currently rely on and plan to continue to rely on a CRO for our Phase 3 trial for GPS in AML and well as all of our ongoing and contemplated clinical studies, with services to be rendered by such CROs and vendors ranging from specific and need- tailored (e. g., data management and biostatistics) ~~only~~ to, in the case of our Phase 3 trial for GPS in AML, all- encompassing. We rely on these parties for the execution of our preclinical studies and clinical trials, including the proper and timely conduct of our clinical trials, and we control only some aspects of their activities. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results or data in a timely manner or may fail to perform at all. While we have agreements governing the commitments of our third- party vendor services, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If **we** ~~our company,~~ or any of our partners or CROs ~~,~~ fail to comply with applicable regulations and **GCP** ~~good clinical practices~~, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our regulatory applications. Upon inspection by a given regulatory authority, such regulatory authority could determine that any of our clinical trials are not in compliance with applicable requirements. In addition, our clinical trials must be conducted with product **candidates** produced under cGMP and other requirements. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within a specified timeframe. Failure to comply also would violate federal requirements in the United States and could result in other

penalties, which would delay the regulatory approval process and result in adverse publicity. Our CROs, third- party vendors and contractors are not our employees, and except for remedies available to us under our agreements with such CROs, third- party vendors and contractors, we cannot control whether or not they devote sufficient time and resources, including experienced staff, to our ongoing clinical, nonclinical and preclinical programs. They may also have relationships with other entities, some of which may be our competitors. If CROs, third- party vendors and contractors do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our current or future product candidates. CRO, vendor or contractor errors could cause our results of operations and the commercial prospects for our current or future product candidates to be harmed, our costs to increase and our ability to generate revenues to be delayed. In addition, the use of third- party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third- party providers. To the extent we are unable to identify and successfully manage the performance of third- party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our third- party CROs, third- party vendors or contractors terminate, we may not be able to enter into arrangements with alternative CROs, third- party vendors or contractors on a timely basis, on commercially reasonable terms or at all. Our CROs, third- party vendors and contractors have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs, third- party vendors and contractors have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third- party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO, third- party vendor or contractor commences work and the new CRO, third- party vendor or contractor may not provide the same type or level of services as the original provider. We have in- licensed a significant portion of our intellectual property from MSK. If we breach our license agreement with MSK, we could lose the ability to continue the development and potential commercialization of GPS. GPS is in- licensed from MSK and includes an exclusive license to U. S. and foreign patent applications. Under the MSK license agreement, we are subject to various obligations, including diligence obligations with respect to funding, development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales, as well as other material obligations. If there is any conflict, dispute, disagreement or issue of nonperformance between us and MSK regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations under any such agreement, we may be liable to pay damages and MSK may have a right to terminate the affected license. The loss of our license agreement with MSK could materially adversely affect our ability to proceed to utilize the affected intellectual property in our development efforts, our ability to enter into future collaboration, licensing and / or marketing agreements for GPS and our ability to commercialize GPS. We rely on a license agreement with GenFleet for the development of ~~GFH009~~ **SLS009**, and if this license is breached or otherwise terminated, we could lose the ability to continue the development and potential commercialization of ~~GFH009~~ **SLS009**. We have entered into a license agreement with GenFleet under which we have an exclusive license to develop and commercialize ~~GFH009~~ **SLS009** worldwide, other than in mainland China, Hong Kong, Macau and Taiwan. Under the license agreement, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones, and royalties on annual net sales (if the product candidate is ultimately commercialized), as well as other material obligations. If there is any conflict, dispute, disagreement, or issue of nonperformance between us and GenFleet regarding our rights or obligations under the license agreement, including any such conflict, dispute, or disagreement arising from our failure to satisfy diligence or payment obligations under the license agreement, we may be liable to pay damages and GenFleet may have a right to terminate the license. The loss of the license agreement could prevent us from developing, commercializing, or entering into future strategic transactions relating to ~~GFH009~~ **SLS009**. The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain and enforce these rights could have a material adverse effect on our business. In addition, our business depends on our ability to license additional therapeutic compounds from third parties. If we fail to meet our obligations under our current license agreements, we may lose the ability to enter into licenses for the development of additional product candidates in the future, which would adversely affect our business. We may not realize the benefits of our strategic alliances that we may form in the future. We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, such as our license agreement with 3D Medicines and our license agreement with GenFleet. These relationships, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety

and efficacy. If we license products or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic alliances or license agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. Our business involves the use of hazardous materials and we and our third- party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do business. Our third- party manufacturers and suppliers' activities involve the controlled storage, use and disposal of hazardous materials. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials even after we sell or otherwise dispose of the products. In some cases, these hazardous materials and various wastes resulting from their use will be stored at our contractors or manufacturers' facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause injury to our employees and others, environmental damage resulting in costly cleanup and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we expect that the safety procedures utilized by our third party contractors and manufacturers for handling and disposing of these materials will generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this will be the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage and our property and casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. We may not be able to establish or maintain the third- party relationships that are necessary to develop or potentially commercialize some or all of our product candidates **, including our relationship with 3D Medicines** . We expect to depend on collaborators, partners, licensees, clinical research organizations and other third parties to support our discovery efforts, to formulate product candidates, to manufacture our product candidates, to conduct clinical trials for some or all of our product candidates and to commercialize our product candidates if approved. For example, in December 2020 we entered into an Exclusive License Agreement with 3D Medicines pursuant to which we granted commercialization rights in Greater China to 3D Medicines. **In accordance with the 3D Medicines Agreement and Side Letter, we expected that 3D Medicines would begin enrolling patients in mainland China in the REGAL study in the second half of 2023. To date, no patients have been enrolled in mainland China. However, patients were enrolled in the REGAL study in Taiwan, which is part of the Greater China territory, prior to the second half of 2023. Thus, we and 3D Medicines are currently engaged in a dispute regarding, among other things, the trigger and payment of the relevant milestone payments due to us as well as 3D Medicines' failure to use commercially reasonable best efforts to develop GPS in the Greater China territory, and particularly in mainland China. Over the last three to four months of 2023, we attempted to resolve the aforementioned matters in good faith under the dispute resolution provisions of the 3D Medicines Agreement with 3D Medicines but we were unable to reach a resolution. Accordingly, we commenced a binding arbitration proceeding administered by the Hong Kong International Arbitration Centre governed by New York State law as per the 3D Medicines Agreement in December 2023.** We **are unable at this time to predict with certainty the outcome of the arbitration proceeding, or the timing of the receipt of any milestone payments and other damages it is seeking in the arbitration proceeding, if at all. Additionally, we** cannot guarantee that we will be able to successfully negotiate **future** agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, vendors and other third parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies and the quality of the preclinical and clinical data that we have generated, and the perceived risks specific to developing our product candidates. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates. We cannot necessarily control the amount or timing of resources that our contract partners, including 3D Medicines, will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. We may not be able to readily terminate any such agreements with contract partners even if such contract partners do not fulfill their obligations to us. In addition, we may receive notices from third parties from time to time alleging that our technology or product candidates infringe upon the intellectual property rights of those third parties. Any assertion by third parties that our activities or product candidates infringe upon the intellectual property rights of third parties may adversely affect our ability to secure strategic partners or licensees for our technology or product candidates or our ability to secure or maintain manufacturers for our compounds. Risks Related to Our Intellectual Property We may not be able to obtain and enforce patent rights or other intellectual property rights that cover our product candidates and that are of sufficient breadth to prevent third parties from competing against us. Our success with respect to our product candidates will depend in part on our ability to obtain and maintain patent protection in the United States and abroad, to preserve our trade secrets, and to prevent third parties from infringing upon our proprietary rights. We seek to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our novel technologies and product candidates that are important to our business. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, we may not pursue or obtain patent protection in all major markets. Moreover, in some circumstances, we do not have the right to control the preparation, filing or prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties or covering technology that a collaboration or commercialization

partner may develop. In some circumstances, our licensors have the right to prosecute and / or enforce the licensed patents without our involvement or consent, or to decide not to enforce or to allow us to enforce the licensed patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If any such licensors fail to maintain such patents, or lose rights to those patents, the rights that we have licensed may be reduced or eliminated and our ability to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign jurisdictions may not protect our 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. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Moreover, the U. S. Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, term, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications, and any collaboration or commercialization partner' s pending and future patent applications, may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. During prosecution of any patent application, the issuance of any patents based on the application may depend upon our or our partners' ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We or any collaboration or commercialization partner may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States or other countries may diminish the value of our or a collaboration or commercialization partner' s patents or narrow the scope of our or their patent protection. Changes in ~~either~~ the patent laws **, regulations,** or ~~in the~~ interpretations **thereof in the United States or abroad may diminish the value** of **our intellectual property. The following are potential factors that could affect the scope our intellectual property: Patent Reform Legislation: The United States Congress periodically considers patent reform legislation aimed at modifying the standards for patentability, patent enforcement procedures, or the rights of patent holders. Such legislative changes could introduce stricter requirements for patent eligibility, limit the scope of patent protection, or streamline patent challenges. Any of these changes may weaken the enforceability or value of our existing patents or make it more difficult to obtain new patents for our products or technologies. Judicial Interpretations: Court decisions, particularly those from the United States Supreme Court and the Federal Circuit, play a crucial role in shaping patent law and practice. Shifts in judicial interpretations, such as alterations to the criteria for patent eligibility or the standard for proving patent infringement, may impact prosecution, defense, and enforcement of certain patent claims in our patent portfolio. International Harmonization: Changes in** patent laws **or regulations** in **foreign jurisdictions where we hold or seek patent protection may also impact the value of our intellectual property. Harmonization efforts or shifts in international standards for patentability criteria, enforcement mechanisms, or patent term extensions could affect our ability to protect and monetize our intellectual property in key markets outside** the United States ~~or abroad may diminish the value of our intellectual property~~ . **Patent Regulations and Patent Office Practices: Alterations in** ~~On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to the U. S.~~ patent **examination procedures or policies at** ~~law. These include provisions that affect~~ the ~~way~~ **United States Patent and Trademark Office, or USPTO, or foreign** patent ~~applications will be prosecuted~~ **offices could influence the strength** and ~~may also affect~~ **scope of our** patent ~~litigation~~ **rights** . **Changes** ~~Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act,~~ in ~~particular the first- to- file provision and our implementation thereof, could increase the uncertainties and costs surrounding the prosecution of our~~ patent **office practices related** ~~applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. In addition, U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances in certain situations. From time~~ to ~~time, the U. S. Supreme Court, other federal courts, the U. S. Congress, or interpretation by the USPTO may change the standards of patentability and any such changes could have a negative impact on our business. Some cases decided by the U. S. Supreme Court have involved questions of when claims reciting abstract ideas, laws of nature, natural phenomena and / or natural products are eligible for a patent, regardless of whether the claimed subject matter is otherwise novel and inventive. These cases include Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U. S. 576 (2013), also known as the Myriad decision; Alice Corp. v. CLS Bank International, 573 U. S. 13- 298 (2014), also known as the Alice decision; and Mayo Collaborative Services v. Prometheus Laboratories, Inc., also known as the Prometheus decision, 566 U. S. 66 (2012). The full impact of these decisions is not yet known. In view of these and subsequent court decisions, the USPTO has issued materials to patent examiners providing guidance for determining the** patent eligibility ~~of claims reciting laws of nature, natural phenomena, or natural products. Our current product candidates include products, or components, derived to various extents from nature; therefore, these decisions and their interpretation by the courts and the USPTO may impact prosecution, defense, and enforcement of certain types of patent claims in our~~ **or patentability standards,** ~~patent portfolio. In addition to increasing uncertainty with regard to our~~ **or the handling** ~~ability to obtain future patents, this combination~~ of ~~events~~ **post- grant proceedings such** ~~has~~ **as inter** ~~created uncertainty with respect to the value of patents~~ -- **partes reviews** , ~~once obtained. Depending on these and other decisions by U. S. Congress, the federal~~

~~courts, and the USPTO, the laws and regulations governing patents could change~~ or **IPRs, may** ~~be interpreted in unpredictable ways that would~~ weaken our ability to obtain some patent claims or to enforce patents that may issue to us in the future. **Moreover** ~~In addition~~ , **changes in regulations governing patent rights, such as** ~~these~~ **those** ~~events~~ **related to government-funded programs,** may **affect our current or future intellectual property rights. While we continuously monitor developments in patent laws and regulations, there can be no assurance that changes in patent laws, regulations, or interpretations thereof will not** adversely affect ~~our ability to defend patents that may issue in procedures in~~ the ~~USPTO~~ **value of** ~~or~~ **our intellectual property** ~~in U. S. courts~~ . While we intend to take actions reasonably necessary to enforce our patent rights, we may not be able to detect infringement of our own or in- licensed patents, which may be especially difficult for methods of manufacturing or formulation products. We depend, in part, on our licensors and collaborators to protect a substantial portion of our proprietary rights. In addition, third parties may challenge our in- licensed patents and any of our own patents that we may obtain, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. Litigation or other proceedings to enforce or defend intellectual property rights is very complex, expensive, and may divert our management' s attention from our core business and may result in unfavorable results that could adversely affect our ability to prevent third parties from competing with us. If another party has reason to assert a substantial new question of patentability against any of our claims in our own and in- licensed patents, the third party can request that the patent claims be reexamined, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential infringement suits, and interference and reexamination proceedings, we may become a party to inter partes and post- grant review proceedings in the United States and patent opposition proceedings outside the United States, where either the patentability of our patents is challenged, or we are challenging the patents of others. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful. As the medical device, biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our commercial product and / or product candidates infringe their patent rights. If a third- party' s patents were found to cover our commercial product and product candidates, proprietary technologies, or our uses, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to continue to commercialize our products or use our proprietary technologies unless we or such collaborators obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief, which could prohibit us from making, using or selling our commercial product and product candidates pending a trial on the merits, which could be years away. ~~GFH009~~ **SLS009** may face generic competition sooner than expected before the expiration of our composition of matter patent protection. Even if we are successful in achieving regulatory approval to commercialize ~~GFH009~~ **SLS009** , our product candidate may face generic competition. **.If we receive positive data from an adequate and well- controlled trial for GFH-009,we will file an NDA in order to receive marketing authorization for GFH009.Once an NDA is approved** ,the product covered thereby becomes a " reference listed drug " in the FDA' s Orange Book.In the United States,manufacturers may seek approval of generic versions of reference listed drugs through submission of an ANDA ~~or approval through a 505 (b) (2) NDA~~ .In support of an ANDA,a generic manufacturer need not conduct clinical trials to assess safety and efficacy.Rather,the applicant generally must show that its product has the same active ingredient (s),dosage form,strength,route of administration and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug,meaning it is absorbed in the body at the same rate and to the same extent.Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices.Thus,following introduction of a generic drug,a significant percentage of the sales of any branded drug is typically lost to the generic product. ~~In contrast,Section 505 (b) (2) enables the applicant to rely,in part,on the FDA' s prior findings of safety and efficacy data for an existing product,or published literature,in support of its application.Section 505 (b) (2) provides an alternate path to FDA approval for new or improved formulations or new uses of previously approved products;for example,a follow- on applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness.~~ Competition that our products could face from **generic** ~~follow- on~~ versions of our products could materially and **adversely affect our future revenue,profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those products.Generic drug manufacturers may seek to launch products following expiration of any applicable exclusivity period we obtain if our products are approved,even if we still have patent protection for such products,We would then enforce our patent rights through commencing an infringement litigation against the generic drug manufacturer.Any such infringement litigation is inherently costly and uncertain** Because ~~GFH009~~ **SLS009** has not been previously approved as an active ingredient, we expect the Hatch- Waxman Act to provide a five- year period of new chemical entity, or NCE, exclusivity following its approval during which time generic competitors cannot file an ~~Abbreviated New Drug Application, or~~ ANDA ~~,~~ for a generic version of ~~GFH009~~ **SLS009 or a 505 (b) (2) NDA for SLS009** , unless the submission contains a Paragraph IV Certification that one or more patents listed in the ~~FDA' s Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the~~ Orange Book ~~)~~ for ~~GFH009~~ **SLS009** are invalid, unenforceable or will not be infringed by a proposed ANDA product, in which case the submission may be made four years following the original drug approval. If a Paragraph IV Certification is made, the ~~generic company~~ **follow- on applicant** is required to provide a Paragraph IV Notice Letter advising of the certification. If that occurs, we will have the opportunity to bring a patent infringement action against the ~~generic company~~ **follow- on applicant** . If such a suit is filed within the 45- day period following receipt of the Paragraph IV Notice Letter, the Hatch- Waxman Act provides for a 30- month stay on FDA' s ability to grant final approval of the proposed ~~generic~~ **follow- on** product. The 30- month stay generally runs from the date the Paragraph IV Notice Letter is received. However, when a Paragraph IV certification is received during the five- year period of NCE exclusivity following the date of first NDA approval, the ~~thirty~~ **30** - month stay extends from five years after the date that product was first approved. The

30- month stay may be shortened or lengthened, including due to a settlement of a lawsuit, a court order (including a decision by the district court on the merits of the case), or patent expiration. The party filing the ANDA **or 505 (b) (2) NDA** may also counterclaim in the litigation that one or more of our patents are invalid, unenforceable, and / or not infringed. If all of the asserted ~~GFH009~~ **SLS009** patents were found invalid, enforceable, and / or not infringed, a competing generic product could be marketed prior to expiration of those patents, our business could be harmed. **Settlements and related licensing agreements resulting from Hatch- Waxman litigation can be challenged and have the potential to generate additional litigation which can be costly. The success of such litigation depends on the strength of the patents covering our branded products and our ability to prove that the follow- on applicant' s product would infringe one or more such patents. The outcome of such litigation is inherently uncertain and may result in potential loss of market exclusivity for SLS009, which may have a significant financial impact on our business. Furthermore, the Federal Trade Commission, or FTC, has brought successful lawsuits challenging Hatch- Waxman litigation settlements as anti- competitive, and such decisions have been upheld by federal circuit courts. If we engage in Hatch- Waxman litigation, we may also face an FTC challenge with respect to any proposed settlement related to such litigation, which may result in additional expense or penalty. The FTC also has more recently been questioning pharmaceutical company patent listings in the Orange Book and raising concerns about " improper " listings that may be intended to discourage competition by follow- on drug developers, and certain members of Congress have been investigating similar issues. Accordingly, there could be future changes to federal laws, regulations, or guidelines related to Hatch- Waxman requirements or procedures that could have a material adverse impact on all pharmaceutical innovators, including us.** If the FDA, EMA or other foreign regulatory authorities approve generic or biosimilar versions of any of our product candidates that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic or biosimilar versions of those products, the sales of our products, if approved, could be adversely affected. Even if we are successful in achieving regulatory approval to commercialize a biologic product candidate ahead of our competitors, our product candidates may face competition from biosimilar and generic products. Most biological products are licensed for marketing by FDA via a BLA, under authorities in the Public Health Service Act, or PHSA. Assuming that we receive positive data from the REGAL trial, we will file a BLA in order to obtain marketing authorization for GPS. ~~To obtain licensure or marketing approval for a new biologic, the sponsor (generally, the manufacturer) must demonstrate in the BLA that the biological product, and that the facility in which it is manufactured, processed, packed, or held, meets standards to assure that the product is safe, pure, and potent. As with other FDA- approved products, any subsequent change to the manufacturing process requires a demonstration to FDA of the comparability of the product' s attributes before and after the change to ensure that the safety and effectiveness of the product is maintained.~~ In 2010, the ~~Biologics Price Competition and Innovation Act, or~~ BPCIA, enacted as Title VII of the ACA **,** established an abbreviated pathway under the PHSA for licensure of biosimilar biologics (i. e., biosimilars, sometimes referred to as follow- on biologics). A biosimilar is a biological product that is demonstrated to be " highly similar " (i. e., biosimilar), but not identical, to an FDA-licensed biological product (i. e., the reference product). The BPCIA also establishes periods of exclusivity for a brand- name biologic (the reference product), one with a duration of ~~4~~ **four** years and the other with a duration of 12 years. These periods of regulatory exclusivity initiate upon licensure of the new biological product if certain requirements are met. During the four- year exclusivity period, an abbreviated BLA for a biosimilar referencing the protected brand- name biologic may not be submitted to FDA. During the 12- year exclusivity period, approval of an abbreviated BLA for a biosimilar referencing the protected brand-name biologic may not be made effective, which means FDA may not approve the biosimilar application until 12 years after the date on which the reference product was first licensed. In addition, the BPCIA provides for a process for disclosure and negotiation between the biosimilar applicant and reference product sponsor, sometimes referred to as the " patent dance. " Although not mandatory on the party of the biosimilar applicant, the dance involves several rounds of informational exchanges concerning potential disputes over the biosimilar applicant' s infringement of the reference product sponsor' s patents. Also, biosimilar licensure under the BPCIA is not contingent upon resolution of patent disputes. Therefore, the FDA may approve a biosimilar despite unresolved patent issues between the reference product sponsor and the biosimilar applicant. We believe that GPS will qualify for four years of data exclusivity and 12 years of market exclusivity under the BPCIA. The law is complex and continues to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates. There is also a risk that the U. S. Congress could amend the BPCIA to shorten the 12- year market exclusivity period or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated after the expiration of our patent protection. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference product in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient- provider relationship and a patient' s specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off- label manner. Even if, as we expect, GPS is considered to be reference products eligible for 12 years of exclusivity under the BPCIA, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved . If we receive positive data from..... infringement litigation is inherently costly and uncertain . In Europe, the European Commission has

granted marketing authorizations for several biosimilar products pursuant to a set of general and product class- specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved. The regulatory, or non- patent, exclusivity available to drugs or biologics in some countries is less than that provided by the United States. For instance, Canada currently provides for an eight- year period of exclusivity for new biological products, and Mexico provides for a five- year period of exclusivity. Furthermore, in some countries outside of the United States, peptide vaccines, such as GPS, are regulated as chemical drugs rather than as biologics and may or may not be eligible for non- patent exclusivity. If competitors are able to obtain marketing approval for biosimilars referencing our therapeutic candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our therapeutic candidates may have received approval. If we are sued for infringing the intellectual property rights of third parties, such litigation could be costly and time- consuming and could prevent or delay our development and commercialization efforts. Our commercial success depends, in part, on us and our collaborators not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and inter partes and post- grant review proceedings before the USPTO and non- U. S. patent offices. Numerous U. S. and non- U. S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our current and future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as our product pipeline grows, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. If any issued third- party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until such patent expired. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. We could be prevented from commercializing a product candidate or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. In addition, parties making claims against us may also obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We may also elect to enter into license agreements in order to settle patent infringement claims prior to litigation, and any such license agreement may require us to pay royalties and other fees that could be significant. During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, programs or intellectual property could be diminished. Accordingly, the market price of our shares of common stock may decline. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on our current and future product candidates in all countries throughout the world would be prohibitively expensive. We or our licensors' intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in countries outside the United States, or from selling or importing infringing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patent (s) to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our licensors have no issued patents or where we do not have exclusive rights under the relevant patent (s), or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to drugs and biologics, which could make it difficult for us and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Certain governments outside the United States have indicated that compulsory licenses to patents may be sought to further their

domestic policies or on the basis of national emergencies. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly, could put our and our licensors' patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuit that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time- consuming and unsuccessful and have a material adverse effect on the success of our business and on our stock price. Third parties may infringe our patents, the patents of our licensors, or misappropriate or otherwise violate our or our licensors' intellectual property rights. We and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent **is** ~~issues~~ **issued** from such applications, and then only to the extent the issued claims cover the technology. In the future, we or our licensors may elect to initiate legal proceedings to enforce or defend our or our licensors' intellectual property rights, to protect our or our licensors' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights or that our intellectual property rights are invalid. In addition, third parties may initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time- consuming. Many of our or our licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. Accordingly, despite our or our licensors' efforts, we or our licensors may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect our rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' patents at risk of being invalidated, held unenforceable or interpreted narrowly. Interference or derivation proceedings provoked by third parties, brought by us or our licensors or collaborators, or brought by the USPTO or any non- U. S. patent authority may be necessary to determine the priority of inventions or matters of inventorship with respect to our or our licensors' patents or patent applications. We may also become involved in other proceedings, such as reexamination, reissue, or opposition proceedings, inter partes review, post- grant review or other pre- issuance or post- grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any such proceeding could require us or our licensors to cease using the related technology and commercializing the affected product candidate, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our or our licensor' s patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current and future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of shares of our common stock. Furthermore, under Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, certain agreements, including patent litigation settlement agreements between brand and generic drug companies, must be filed with the FTC and DOJ. The Patient Right to Know Drug Prices Act amended MMA Title XI, expanding the reporting requirements to include agreements between biosimilar product applicants and biologic companies. Although we have taken steps to protect our trade secrets and unpatented know- how ~~,~~ by entering into confidentiality agreements with third parties ~~,~~ and proprietary information and invention agreements with **our employees and** certain ~~employees,~~ consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets and unpatented know- how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know- how is expensive and time- consuming, and the outcome is unpredictable. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their other clients or former employers. As is common in the biotechnology and pharmaceutical industry, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our commercial product and product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these types of

claims. Even if we are successful in defending against any such claims, any such litigation would likely be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome. If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected, and our business could be harmed. Proprietary trade secrets and unpatented know- how are also very important to our business. We ~~also~~ have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. **We** ~~In addition to seeking the protection afforded by patents, we~~ rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our current or future product candidates, thus eroding our competitive position in the market. Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the United States. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition. Some intellectual property that we have in- licensed, if created as a result of government funded programs, may be subject to certain federal regulations. Some of the agreements covering the intellectual property rights we have licensed provide that to the extent that such rights are derived from the use of U. S. government funding, those rights may therefore be subject to certain federal regulations. As a result, the U. S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh- Dole Act of 1980, or Bayh- Dole Act. These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us to grant exclusive, partially exclusive or non- exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as" march- in rights"). The U. S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. **Moreover, changes in regulations related to government-funded programs may affect how the government may exercise march- in rights and affect any of our current or future intellectual property rights derived from U. S. government funding.** Risks Related to **Competition and** Commercialization of Our Current and Future Product Candidates **We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development, and commercialization of our product candidates. Our competitors may succeed in developing competing products before we do for the same indications we are pursuing, obtaining regulatory approval for products, or gaining acceptance for the same markets that we are targeting. If we are not " first to market " with a product candidate, thereby effecting our order of entry, our competitive position could be compromised via reduced market share and higher hurdles to regulatory approval. We expect any product candidate which we commercialize will compete with products from other companies in the biotechnology and pharmaceutical industries. There are several biopharmaceutical companies which have approved treatments options in the United States for AML broadly, with different mechanisms of action, including AbbVie / Genentech (Venclexta), Pfizer (Mylotarg), Daiichi- Sankyo (Vanflyta), Rigel Pharmaceuticals (Rezlidhia) and Bristol Myers Squibb (Vidaza). Key late- stage pipeline agents that are different from GPS have been granted ODD or Fast Track designation due to the unmet need in AML. Therefore, clinical late- stage companies developing late- stage clinical candidates to treat r / r AML may enter the market before our potential products, such as GlycoMimetics**

(uproleselan), Delta- Fly Pharma (DFP- 10917), and AROG Pharmaceuticals (crenolanib). A key competitor may be Iomab- b, which is being developed by Actinium Pharmaceuticals. In late 2022 / early 2023, Actinium announced positive results in its pivotal Phase 3 trial in adults aged 55 and above with active r / r AML. With respect to WT1- targeting therapies, we do not believe GPS currently has direct competition in AML in the maintenance setting after CR2. There are companies engaged in the clinical development of WT- 1 targeting therapies; however, they are not focused on AML at this time, including Astellas (ASP7517) and Cue Biopharma (CUE- 102), or are in earlier stages, such as NexImmune (NEXI- 001). With respect to our SLS009 program, we anticipate competition with MEI Pharma, whose voruciclib is in a Phase 1 clinical trial as a monotherapy and in combination with venetoclax for adults with r / r AML. There may also be competition in one of our other indications, PTCL, from enitociclib, a CDK9 inhibitor under development by Vincerx Pharma as a monotherapy and in combination with venetoclax for the treatment of PTCL. Furthermore, there are other companies which are in early development stages for their CDK9 inhibitors and targeting other hematological malignancies or solid tumors, including Kronos Bio (KB- 0742), Sumitomo Dainippon Pharma (TP- 1287), Adastra Pharmaceuticals (zotiraciclib), and Prelude Therapeutics (PRT2527). Many of our competitors have substantially greater commercial infrastructures and financial, technical and personnel resources than we have. In addition, some are farther along in their clinical development programs or in collaboration with larger, established pharmaceutical companies. We may not be able to compete unless we successfully: • design and develop products that are superior to other products in the market; • conduct successful preclinical and clinical trials; • attract qualified scientific, medical, sales and marketing and commercial personnel; • obtain patent and / or other proprietary protection for our processes and product candidates; • obtain required regulatory approvals; and • collaborate with others in the design, development, and commercialization of new products. Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability, and safety to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer. If we obtain marketing approval, our commercial success depends on establishing or implementing our own sales, marketing, **access and reimbursement,** and distribution capabilities or entering into licensing or collaboration agreements for these purposes, and the timing of these. With the exception of very few employees, including our executive officers, we ~~do~~ **have** not yet ~~have~~ **built** a broader team with any significant sales, marketing **, access and reimbursement,** or distribution experience. If we progress toward regulatory approval, we will take an efficient and measured approach to building ~~our~~ **an appropriately sized** commercial infrastructure **depending on whether we choose** to commercialize our current and any future product candidates on our own ~~,~~ **or** through licensing **, distribution** or collaboration agreements. We will have to invest significant amounts of financial and management resources, some of which will be committed prior to the receipt of positive data **if we choose to commercialize on our own** . We may need to successfully recruit, retain and train **a broad complement of** effective **commercial staff, including, but not limited to,** sales **, access** and ~~marketing~~ **reimbursement, business analytics, and diagnostics. As AML is a highly competitive space, we would expect some** personnel **to** ~~, some of whom may~~ be sought by our competitors. Any delays in hiring an adequate number of experienced sales personnel (including support staff), inability to obtain access to key markets, and unforeseen time, cost and expenses associated with creating a separate and high performing sales and marketing organization could adversely impact commercialization of any product for which we obtain marketing approval. We may elect to utilize **other means of commercialization should the economics of the approach be deemed appropriate. This could include** contract sales forces or strategic partners to support in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates, or do so in a timely manner, or may be unable to do so on terms that are favorable to us. We may also need the infrastructure and resources to maintain the contractual relationships and external support. If we are not able to timely and properly establish a commercial organization on our own or in collaboration with third parties, then we may not be profitable. Our commercial success depends upon attaining significant market acceptance of our current and future product candidates, if approved, among health care providers, third- party payors and operators of major cancer clinics. Even if we obtain regulatory approval for any of our current or future product candidates, the products may not gain market acceptance among physicians, third- party payors, patients or the medical community. For example, current cancer treatment such as chemotherapy and radiation therapy are well- established in the medical community, and health care providers may continue to rely on these treatments. The degree of market acceptance of any product candidates for which we receive approval depends on a number of factors, including: • the efficacy and safety of such product candidates as demonstrated in clinical trials, and acceptance of such by physicians, major cancer treatment centers, and patients; • the potential and perceived advantages and disadvantages of product candidates over alternative treatments, including the degree of clinically meaningful improvement in care, ease of administration and prevalence and severity of side effects; • the clinical indications and patient populations for which the product candidate is approved and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the ability to garner placement of our therapeutics in widely accepted clinical practice treatment guidelines; • **the placement, or the lack of placement, of our therapeutics in reputable and highly regarded clinical treatment guidelines; •** product labeling or product insert requirements of the FDA or other regulatory authorities and any restrictions on use with other medications; • the timing of market introduction of our products as well as competitive products; • the cost of treatment and coverage and reimbursement status; ~~and~~ • development and effectiveness of our sales and marketing, manufacturing and distribution efforts for commercial scale **; and • new healthcare legislation that**

could adversely affect the payor profile of our marketed assets . If any of our current and future product candidates are approved but fail to achieve market acceptance, we will not be able to generate significant revenues, which would compromise our ability to become profitable. Even if we are able to commercialize our current or future product candidates, the products may become subject to unfavorable pricing regulations, third- party reimbursement practices or health care reform initiatives, which could harm our business. Significant uncertainty exists as to the coverage and reimbursement status of any drug or biological candidates for which we obtain regulatory approval. The regulations that govern marketing approvals, pricing and reimbursement **(public and private)** for new drug products vary widely from country to country. In the United States, recently passed legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize any product successfully will also 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 cover and how much they will pay. A primary trend in the U. S. health care industry and elsewhere is cost containment. Government authorities and third- party have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar foreign regulatory authorities outside the United States. Moreover, eligibility for coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. ~~Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent.~~ Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third- party **commercial** payors often follow CMS coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. **Further, there have been, and may continue to be, legislative and regulatory proposals at the U. S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of health care. The continuing efforts of the government, insurance companies, managed care organizations and other third- party payors to contain or reduce costs of health care may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability. More recently, in August 2022, President Biden signed into the law the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product' s price increases faster than the rate of inflation. This calculation is made on a drug product- by- drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. Additional state and federal health care reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for certain biopharmaceutical products or additional pricing pressures. In some foreign countries, particularly the member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a drug candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after**

reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, we may be required to conduct additional clinical trials that compare the cost- effectiveness of our drug candidates to other available therapies in order to obtain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to successfully commercialize and achieve or sustain profitability for sales of any of our drug candidates that are approved for marketing in that country and our business could be adversely affected. Health care policy changes may have a material adverse effect on our business and results of operations. Our business may be affected by the efforts of government and third- party payors to contain or reduce the cost of health care through various means. For example, the **recently enacted** ~~Inflation Reduction Act of 2022 (~~ IRA ~~)~~ requires drug manufacturers to pay a rebate to the federal government if prices for single- source drugs and biologicals covered under Medicare Part B and nearly all covered drugs under Part D increase faster than the rate of inflation (CPI- U **Penalty**). The Patient Protection and Affordable Care Act, and the Health Care and Education Affordability Reconciliation Act of 2010 ~~(~~**, or** collectively, the ~~Affordable Care Act or~~ ACA ~~)~~, enacted in March 2010, substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry ~~. With regard to pharmaceutical products~~ , **by** among other things, ~~the ACA is expected to expand and increase~~ **increasing** ~~industry~~ **the minimum Medicaid** rebates ~~for drugs covered~~ **owed by most manufacturers** under **the** Medicaid **Drug Rebate** ~~programs and make changes to the coverage requirements under the Medicare Part D program~~ **Program ; introducing** ~~. The Supreme Court upheld the ACA in the main challenge to the constitutionality of the statute in 2012. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015. While other challenges remain to portions of the ACA, these two cases were generally viewed as the only existential threats to the statute that have been raised so far. Proposals such as expanding the Medicaid drug rebate program to the Medicare Part D program, providing authority for the government to negotiate drug prices under the Medicare Part D program and lowering reimbursement for drugs covered under the Medicare Part B program have been presented to Congress in 2016, including by the current Administration, but implementation likely will be challenging in light of strong opposition to these proposals as well as the current political climate. The Administration can rely on its existing statutory authority to make policy changes that could have an impact on the drug industry. For example, the Medicare program has proposed to test alternative payment methodologies for drugs covered under the Part B program. In general, we cannot predict the impact that the ACA or any other legislative or regulatory proposals will have on our business. Regardless of whether or not the ACA is changed or modified by Congress or the Supreme Court, we expect both government and private health plans to continue to require health care providers, including health care providers that may one day purchase our products, to contain costs and demonstrate the value of the therapies they provide. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the health care system that could prevent or delay marketing approval of our current product candidates and any future product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements, additions or modifications to product labeling, the recall or discontinuation of our products, or additional record- keeping or reporting requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the United States, there have been and continue to be a number of legislative initiatives to contain health care costs. For example, the ACA substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U. S. biopharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower- cost biosimilars, addressed~~ a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs ~~and biologics~~ that are inhaled, infused, instilled, implanted or injected **; extending** ~~, increased the minimum Medicaid rebates owed by manufacturers under~~ the Medicaid Drug Rebate Program ~~and extended the rebate program~~ to **utilization of prescriptions of** individuals enrolled in Medicaid managed care **plans; imposing mandatory discounts for** ~~organizations, established annual fees and taxes on manufacturers of~~ certain ~~branded prescription drugs and biologics, and created a new~~ Medicare Part D **beneficiaries as a condition for** ~~coverage gap discount program, in which~~ manufacturers ~~must agree to offer 70 % (increased from 50 % pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point- of- sale discounts off negotiated prices of applicable brand drugs and biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer~~ ’ ~~s~~ outpatient drugs ~~or biologics to be covered~~ - **coverage** under Medicare Part D ~~. Since its enactment,~~ **; and establishing a Center for Medicare Innovation at** ~~there~~ -- **the CMS** ~~have been judicial, executive and Congressional challenges~~ to ~~certain aspects~~ **test innovative payment and service delivery models to lower Medicare and Medicaid spending. Regardless** of **whether or not** the ACA **is changed or modified by Congress or** ~~. However, following several years of litigation in the federal courts, in June 2021,~~ the U. S. Supreme Court ~~upheld~~ **, we expect both government and private health plans to continue to require health care providers, including health care providers that may one day purchase our products, to contain costs and demonstrate the value of the therapies** ~~the~~ **they provide. In addition** ~~ACA when it dismissed a legal challenge~~ to the ~~ACA~~ **IRA** ’ ~~s constitutionality. Further legislative and regulatory changes under~~ **drug price negotiation provisions summarized above (see** the **risk factor herein entitled “ Even if we are able to commercialize** ~~ACA remain possible, but it is unknown what form any such changes or~~ **our current** ~~any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our~~ - **or** ~~business in the~~ future **product candidates** ~~. We expect that changes or additions to the ACA~~ , ~~the Medicare and Medicaid programs and changes stemming from other~~ -- **the products may become subject to unfavorable pricing regulations, third- party reimbursement practices or** health care reform ~~measures~~

initiatives , ~~especially with regard~~ **which could harm our business. "), President Biden' s Executive Order 14087, issued in October 2022, called for the CMS Innovation Center** to ~~health care~~ **prepare and submit a report to the White House on potential payment and delivery modes that would complement the IRA, lower drug costs, and promote** access **to innovative drugs. In February 2023** , ~~financing~~ **CMS published its report which described three potential models focusing on affordability, accessibility and feasibility of implementation** ~~or~~ **for further testing by** ~~other~~ -- **the** ~~legislation in individual states~~ **CMS Innovation Center. As of January 2024** , ~~could~~ **the CMS Innovation Center continues to test the proposed models and develop implementation plans. Such models, if implemented, may** have a **significant impact** ~~material adverse effect~~ on the **distribution of** ~~health care industry in the United States. In addition, other legislative changes have been proposed~~ and **reimbursement for our product candidates** ~~adopted in the United States since the ACA~~ that **receive FDA approval** ~~affect health care expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year pursuant to the Budget Control Act of 2022~~ , **if any.** ~~which began in 2013 and was extended by the Consolidated Appropriations Act for 2023, and will remain in effect through 2023, unless additional~~ **Additionally** ~~Congressional action is taken. Further~~ , there has been heightened governmental scrutiny in the United States of **pharmaceutical** ~~drug and biological product~~ pricing practices **considering** ~~in light of~~ the rising cost of prescription drugs **and biologics** . Such scrutiny has resulted in several ~~recent~~ congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. ~~In~~ **For example, in** May 2019, ~~DHHS~~ **CMS** issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This **final** rule codified ~~a DHHS~~ **CMS' s** policy change that was effective January 1, 2019. ~~More recently~~ **In addition** , **the** ~~in August 2022~~ **2021** ~~, President Biden~~ **Consolidated Appropriations Act** signed into ~~the~~ law **on December 27,** ~~the Inflation Reduction Act of 2022~~ **2020** , **incorporated extensive health care** ~~or the IRA. Among other things, the IRA has multiple~~ provisions **and amendments to existing laws, including a requirement** that **all manufacturers** ~~may impact the prices~~ of drug products **covered under** ~~that are both sold into the~~ Medicare ~~program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts~~ -- **Part** B **report** ~~or D must pay a rebate to~~ the ~~federal government if the drug~~ product' s **average sales** price **to CMS beginning** ~~increases faster than the rate of inflation. This calculation is made~~ on **January 1** ~~a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally~~ , ~~starting in payment year 2026~~ **2022** , **subject to enforcement via civil money penalties** ~~CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease~~ . Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control biopharmaceutical 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 **. For example, in recent years, several states have formed PDABs. Much like the IRA' s drug price negotiation program, these PDABs have attempted to implement upper payment limits on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado' s PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits** . In December 2020, the U. S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers, or PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. In addition, the **FTC** ~~Federal Trade Commission~~ in mid- 2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us. We expect that ~~the~~ **these** ~~ACA, the recent laws described above,~~ and other health care reform measures that may be adopted in the future may result in additional reductions in Medicare and other health care funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care and / or impose price controls may adversely affect: • the demand for our product candidates, if we obtain regulatory approval; • our ability to receive or set a price that we believe is fair for our products; • our ability to generate revenue and achieve or maintain profitability; • our ability to enjoy or maintain market exclusivity; • the level of taxes that we are required to pay; and • the availability of capital. **On January 5, 2024, the FDA granted approval to Florida for the importation of specific prescription medications from Canada. This initiative aims to provide residents of Florida with access to more affordable drug prices comparable to those paid by Canadians. The noteworthy aspect of this announcement lies in it being the inaugural instance where the FDA has officially sanctioned a state to securely import prescription drugs from an international source. Should this trend of parallel importing grow within the U. S. markets, net revenues could be adversely affected.** Price controls may be imposed in foreign markets, which may adversely affect our future profitability. In some countries, particularly member states of the **EU** ~~European Union~~ , the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other

stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. **Global** ~~Reference~~ **reference** pricing used by ~~various European Union~~ **most (if not all) EU** member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected. Risks Related to Health Care Compliance Regulations Our relationships with customers and third- party payors will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. If we or they are unable to comply with these provisions, we may become subject to civil and criminal investigations and proceedings that could have a material adverse effect on our business, financial condition and prospects. Health care providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with health care providers, health care entities, third- party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we research, develop and will market, sell and distribute our products. As a biopharmaceutical company, even though we do not and will not control referrals of health care services or bill directly to Medicare, Medicaid or other third- party payors, federal and state health care laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. Restrictions under applicable federal and state health care laws and regulations that may affect our ability to operate include the following: • the federal health care Anti- Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare or Medicaid; • federal civil and criminal false claims laws, including the **FCA** ~~federal False Claims Act~~ that can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • ~~the federal Health Insurance Portability and Accountability Act of 1996, or~~ HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any health care benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for health care benefits, items or services, **and further,** as amended by ~~the Health Information Technology for Economic and Clinical Health Act of 2009, or~~ HITECH, ~~which~~ imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain health care providers, health plans, and health care clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information; • the federal physician sunshine requirements under the ACA which requires certain manufacturers of drugs, devices, biologics and medical supplies, with certain exceptions, to report annually to HHS information related to payments and other transfers of value to physicians, certain **advanced** non- physician health care practitioners, and teaching hospitals, and ownership and investment interests held by physicians and other health care providers and their immediate family members and applicable group purchasing organizations; • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non- governmental third- party payors, including private insurers; some state laws which require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers, marketing expenditures or pricing information; and certain state and local laws which require the registration of pharmaceutical sales representatives; and • state and foreign laws govern the privacy and security of health information in specified circumstances, including the GDPR, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded health care programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any physicians or other health care providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs. Many health care laws and regulations are rapidly changing and legislative bodies and regulatory agencies are regularly considering amendments and supplements to existing laws and regulations, and as a result interpretations of rules and confirmation of our compliance with such rules can be ambiguous. **We may be subject to, or may in the future become**

subject to, U. S. federal and state, and international laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such evolving privacy and data protection laws could adversely affect our business, results of operations, and financial condition. New privacy and data security laws have been proposed in more than half of the states in the United States and in the U. S. Congress, reflecting a trend toward more stringent privacy legislation in the U. S., which trend may accelerate with increasing concerns about individual privacy. The existence of comprehensive privacy laws in different states in the U. S. may make our compliance obligations more complex and costly, may require us to modify our data processing practices and policies, and may require us to incur substantial costs and potential liability in an effort to comply. In California, the CCPA, which became effective in 2020, broadly defines personal information, gives California residents expanded individual privacy rights and protections, provides for civil penalties for violations, and gives California residents a private right of action for data breaches in certain cases. Further, the California Privacy Rights Act, or the CPRA, which became effective in 2023 and amends the CCPA, imposes additional obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California Privacy Protection Agency authorized to issue substantive regulations and is expected to result in increased privacy and information security enforcement. The CPRA also extends the provisions of both the CCPA and the CPRA to the personal information of California- based employees. While there is an exception for certain health information, including protected health information that is subject to HIPAA, and clinical trial data, the CCPA may impact our business activities if we become a " Business " regulated by the CCPA. Further, there continues to be some uncertainly about how certain provisions of the CCPA will be interpreted and how some areas of the law will be enforced. We will continue to monitor developments related to the CCPA and anticipate additional costs and expenses associated with compliance. In addition to the CCPA, broad consumer privacy laws recently went into effect in Virginia on January 1, 2023, in Colorado and Connecticut on July 1, 2023, and in Utah on December 31, 2023. New privacy laws will also become effective in Florida, Montana, Oregon, and Texas in 2024, in Delaware, Iowa, New Hampshire, New Jersey, and Tennessee in 2025, and in Indiana in 2026. In addition, numerous other states are considering new comprehensive privacy laws. Other U. S. states, such as New York and Massachusetts have enacted stringent data security laws and numerous other states have proposed similar laws. Additionally, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California' s patient privacy laws, for example, provide for penalties of up to $ 250, 000 and permit injured parties to sue for damages. Similarly, as discussed above, the CCPA allows consumers a private right of action when certain personal information is subject to unauthorized access and exfiltration, theft or disclosure due to a business' failure to implement and maintain reasonable security procedures. Furthermore, over the past few years, the number of privacy- related enforcement actions in the U. S., and in many cases the fines, have steadily increased. Failure to comply with these current and future laws, policies, industry standards, or legal obligations. or any data breach involving personal information, may result in government enforcement actions, litigation, fines, and penalties, private litigation, or adverse publicity, and could cause our customers, business partners, and investors to lose trust in us which could have a material adverse impact on our business, results of our operations, and our financial condition. We continue to face uncertainty as to the exact interpretation of the new requirements on our clinical trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, for the treatment of genetic data, along with increased customer demands for enhanced data security infrastructure, could greatly increase our cost of providing our products, decrease demand for our products, reduce our revenues and / or subject us to additional liabilities. In many activities, including the conduct of clinical trials and our regulatory and commercial operations in the EEA and the United Kingdom, or UK, we are subject to international laws and regulations governing data privacy and the protection of health- related and other personal information. The regulatory framework for collecting, using, safeguarding, sharing, transferring and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. The withdrawal of the UK from the EU and the subsequent separation of the data protection regimes of these territories means we are required to comply with separate data protection laws in the EU and the UK, which may lead to additional compliance costs and could increase our overall risk. Similar laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which took effect across all Member States of the EEA on May 25, 2018, and as still in effect in the UK as the UK GDPR. On June 28, 2021, the EU Commission adopted decisions on the UK' s adequacy under the EU GDPR, and the UK continues to operate under this adequacy

decision. The GDPR applies to any company established in the EU as well as to those outside the EU that process personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. We currently conduct clinical trials and engage in regulatory and commercial operations in the EEA and the UK. As a result, we are subject to privacy laws, including the GDPR and UK GDPR. The GDPR imposes a broad range of data protection obligations on controllers and / or processors, as applicable, that must be complied with when processing personal data subject to the GDPR, including, for example, providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be " forgotten " and rights to data portability, as well as enhanced current rights (e. g., access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; limitations on retention of information; mandatory data breach notification requirements;; safeguards to protect the security and confidentiality of personal data; restrictions on transfers of personal data outside of the EU to third countries deemed to lack adequate privacy protections (such as the U. S.), and onerous new obligations and liabilities on services providers or data processors.. In particular, medical or health data, genetic data and biometric data are all classified as " special category " data under the GDPR and afford greater protection and require additional compliance obligations. Further, the UK and EU member states have a broad right to impose additional conditions — including restrictions — on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). Non- compliance with the GDPR may result in monetary penalties of up to € 20 million or 4 % of worldwide revenue, whichever is greater. Moreover, data subjects can claim damages resulting from infringement of the GDPR. The GDPR further grants non- profit organizations and consumer organizations the right to bring claims on behalf of data subjects. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we may operate in. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual EU Member States. Compliance with the GDPR is a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our EU activities. Further, as referenced above, following the UK' s withdrawal from the EU (i. e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the EU GDPR has been implemented in the UK (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs. Non- compliance with the UK GDPR may result in monetary penalties of up to £ 17. 5 million or 4 % of worldwide revenue, whichever is higher. In addition, we may be unable to transfer personal data from the EU, UK, and other jurisdictions to U. S or other countries due to limitations on cross- border data flows. In particular, the EEA and the UK have significantly regulated the transfer of personal data to the U. S and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and the UK to the U. S. in compliance with law, such as the EEA and UK' s standard contractual clauses and the newly- adopted Data Privacy Framework, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U. S.. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the U. S., or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and the UK to other jurisdictions, particularly to the U. S., are subject to increased scrutiny from regulators, individual litigants, and activist groups. If we are investigated by an EEA or UK data protection authority, we may face fines and other penalties, which could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by EEA, UK, or multi- national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure because of the current (and future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR and UK GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operations. In addition, many jurisdictions outside of the EEA and the UK are also considering and / or enacting comprehensive data protection legislation. For example, as of August 2020, the

Brazilian General Data Protection Law imposes stringent requirements similar to GDPR with respect to personal information collected from individuals in Brazil. In China, there have also been recent significant developments concerning privacy and data security. The Data Security Law of the People' s Republic of China (Data Security Law), which took effect on September 1, 2021, requires data processing (which includes the collection, storage, use, processing, transmission, provision and publication of data), to be conducted in a legitimate and proper manner. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data processing activities and also introduces a data classification and hierarchical protection system based on the importance of data in economic and social development and the degree of harm it may cause to national security, public interests, or legitimate rights and interests of individuals or organizations if such data are tampered with, destroyed, leaked, illegally acquired or illegally used. The appropriate level of protection measures is required to be taken for each respective category of data. Also in China, the Personal Information Protection Law, which took effect on November 1, 2021, introduced stringent protection requirements for processing personal information, which are in many ways akin to the requirements of the GDPR. We may be required to make further significant adjustments to our business practices to comply with the personal information protection laws and regulations in China including the Personal Information Protection Law. We also continue to see jurisdictions imposing data localization laws. These regulations may interfere with our intended business activities, inhibit our ability to expand into those markets or prohibit us from continuing to offer services in those markets without significant additional costs. Because the interpretation and application of many domestic and international privacy and data protection laws, commercial frameworks, and standards are uncertain, it is possible that these laws, frameworks, and standards may be interpreted and applied in a manner that is inconsistent with our existing data management practices and policies. It is also possible that by complying with one law, we may be violating another. In addition to the possibility of fines, lawsuits, breach of contract claims, and other claims and penalties, we could be required to fundamentally change our business activities and practices or modify our solutions, which could have an adverse effect on our business. Failure to comply with current and future privacy and data protection laws and regulations could result in government enforcement actions (including the imposition of significant penalties), criminal and civil liability for us and our officers and directors, private litigation and / or adverse publicity that negatively affects our business. Any inability to adequately respond to privacy and security concerns, even if unfounded, or to comply with applicable privacy and data protection laws, regulations, and policies, could result in additional cost and liability to us, damage our reputation, inhibit our ability to conduct trials, and adversely affect our business. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded health care programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations ~~. In the past, we have been involved in multiple legal and governmental proceedings, including securities class action litigation, and may in the future be involved in proceedings, relating to the commercial activities of our predecessor that could divert management' s attention and adversely affect our financial condition and our business. In the past, our predecessor, Galena, was involved in multiple legal and governmental proceedings, including stockholder class actions, both state and federal, none of which are ongoing. These legal and governmental actions, or the Galena Legacy Matters, included allegations relating to federal securities law violations, claims under the False Claims Act and Anti- Kickback Statute, claims regarding breaches of contract, and other stockholder allegations, including claims of breaches of fiduciary duty by our former directors, and fentanyl related litigation. Additionally, securities class action or stockholder derivative litigation has become common in our industry following the announcement of negative data or adverse events. We have in the past, and may in the future, become involved in this type of litigation. Litigation often is expensive and diverts management' s attention and resources, which could adversely affect the continuing company' s business. There has been significant litigation and governmental activity generally in the fentanyl and opioid area, and this activity may continue in the future. We cannot assure you we will not become subject to additional legal or governmental proceedings relating to Galena' s former Abstral business in the future. Moreover, we may be exposed to claims, or other legal or governmental actions in the future relating to violations of the False Claims Act, Anti- Kickback Statute, the ACA, or any other applicable state or federal statutes or regulations, and thereby be subject to penalties, such as civil and criminal penalties, damages, fines, or an administrative action of exclusion from government health care reimbursement programs. Since DOJ published a memorandum in 2016 formally instructing prosecutors to focus on individual accountability when dealing with corporate misconduct, individual prosecutions have increased. Future legal and governmental proceedings may not qualify for coverage under, or may exceed the limit of, our applicable directors and officers liability insurance policies and could have a material adverse effect on our financial condition, liquidity, and results of operations. An unfavorable outcome in any future~~

~~litigation matters could damage our business and reputation. We can make no assurances as to the time or resources that would need to be devoted to any new or future litigation matters or their outcome, or the impact, if any, that these matters may have on our business or financial condition~~ . Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our current or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or products that we may develop; • termination of clinical trial sites or entire clinical trial programs; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards to trial subjects or patients; • loss of revenue; • diversion of management and scientific resources from our business operations; and • the inability to commercialize any products that we may develop. We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. In addition, even in instances where we have insurance coverage, our insurance carriers may deny coverage, which could lead to the inability to recover for certain losses and costly insurance coverage disputes with our carriers. Risks Related to our Business Operations ~~A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID- 19 pandemic, could materially and adversely affect our business. Public health crises such as pandemics or similar outbreaks could adversely impact our business. Notably, the COVID- 19 pandemic continues to evolve. The extent to which COVID- 19 impacts our operations or those of our collaborators, contractors, suppliers, CROs, clinical sites, CMOs and other material business relations and governmental agencies will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the virus and the actions to contain it or treat its impact, among others. Previously, our clinical trial operations were directly and indirectly adversely impacted, and could continue to be directly and indirectly adversely impacted, by the COVID- 19 pandemic. The spread of COVID- 19 could also have adverse economic impacts to us. While the potential economic impact brought by, and the duration of, the COVID- 19 pandemic, have been, and continue to be, difficult to assess or predict, the spread of COVID- 19 has caused a broad impact globally. The ongoing COVID- 19 pandemic continues to evolve. The extent to which the COVID- 19 pandemic may impact our business continues to be highly uncertain and cannot be predicted with confidence.~~ If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reports, which would harm our business, the trading price of our common stock and our ability to raise additional capital in the future. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock, and which could impact our ability to raise capital in the future. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act of 2002, as amended, or SOX, or any required subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. We are required, pursuant to Section 404 of SOX, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of December 31, ~~2022~~ **2023** . However, our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the guidelines in the Internal Control- Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, ~~2022~~ **2023** . An independent assessment of the effectiveness of our internal controls could detect problems that our management' s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation ~~. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development, and commercialization of our product candidates. Our competitors may succeed in developing competing products before we do for the same indications we are pursuing, obtaining regulatory approval for products, or gaining acceptance for the same markets that we are targeting. If we are not " first to market " with a product candidate, thereby effecting our order of entry, our competitive position could be compromised via reduced market share and higher hurdles to regulatory approval. We expect any~~

~~product candidate which we commercialize will compete with products from other companies in the biotechnology and pharmaceutical industries. For example, there are several biopharmaceutical companies who are currently marketing therapies to treat AML and are approved treatments in the United States. There are also many companies in various clinical stages which are developing therapies to treat AML, including the following which are late- stage: GlycoMimetics (uproleselan); Actinium Pharmaceuticals (Iomab- B); Delta- Fly Pharma (radgocitabine); Gilead (magrolimab); Daiichi Sankyo (VANFLYTA / quizartinib); and AROG Pharmaceuticals (crenolanib). With respect to our GPS program, we expect to compete with companies who are also developing WT1 targeting therapies to treat AML, such as Astellas (ASP7517), BMS (JTCR016), NexImmune (NEXI- 001), Roche (RG63441 / RO7283420), and Cue Biopharma (CUE- 102). With respect to our GHF009 program, we anticipate competition with companies who are investigating CDK9 targeting therapies to treat AML and our other potential indications, such as Vincerx (VIP152), AstraZeneca (AZD4573), Kronos Bio (KB- 0742), Sumitomo Dainippon Pharma (TP- 1287), MEI Pharma, Inc. (Voruciclib) and Prelude Therapeutics (PRT2527). Many of our competitors have substantially greater commercial infrastructures and financial, technical and personnel resources than we have. In addition, some are farther along in their clinical development programs or in collaboration with larger, established pharmaceutical companies. We may not be able to compete unless we successfully: • design and develop products that are superior to other products in the market; • conduct successful preclinical and clinical trials; • attract qualified scientific, medical, sales and marketing and commercial personnel; • obtain patent and / or other proprietary protection for our processes and product candidates; • obtain required regulatory approvals; and • collaborate with others in the design, development, and commercialization of new products. Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability, and safety to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer~~ . We enter into various contracts in the normal course of our business in which we may be required to indemnify the other party to the contract under certain specific scenarios. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations. In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically agree to indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our collaboration agreements, we indemnify our collaborators from any third- party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we indemnify them from claims arising from the good faith performance of their services. Should our obligations under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage for any claim, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage for the claim or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected. Significant disruptions of information technology systems, computer system failures or ~~breaches of information security~~ **cybersecurity incidents** could adversely affect our business. We rely to a large extent upon sophisticated information technology networks and systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we **rely on** ~~are managing many independent vendor relationships with~~ third parties **that process** ~~who may or could have access to our~~ confidential information **on our behalf. This includes information technology systems of MSK, our CROs, our CMOs, and other business vendors on which we rely** . The size and complexity of our information technology and information security systems, and those of our third- party vendors with whom we contract ~~(~~**,** and the ~~large amounts of~~ confidential information ~~that is present on them)~~ **and data stored or processed thereon** , make such systems potentially vulnerable to **computer viruses, bugs, worms,** ~~service interruptions or to security breaches from inadvertent or intentional actions by our~~ **or other** ~~employees or vendors, or from~~ malicious **codes, malware, including as a result of advanced persistent threat intrusions, and other** attacks by **computer hackers, cracking, application security attacks, social engineering, including through phishing attacks, supply chain attacks and vulnerabilities through our** third ~~parties~~ **- party service providers, denial- of- service attacks, such as credential stuffing, credential harvesting, personnel misconduct or error, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats** . Such attacks are of ever- increasing levels of sophistication and are made by groups, including nation states and organized crime, and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data. While we have invested significantly in the protection of data and information technology, there can be no assurance that we will be able to detect any such disruption or ~~security~~ **cybersecurity** ~~breach~~ **incident** in a timely manner or at all **,** or that our efforts will prevent service interruptions or **cybersecurity incidents. While we have implemented** security **measures** ~~breaches. Our internal computer systems~~ , ~~and those of MSK,~~ **there can be no assurances that a cybersecurity incident** ~~our~~ **or any** ~~CROs, our CMOs, and~~ other **previously identified threats will not occur. Any such event could have a material adverse effect upon our reputation,** business ~~vendors on which we rely~~ , **operations** ~~are vulnerable to damage from~~

~~computer viruses~~ , ~~unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our~~ **or financial condition** ~~vulnerability to problems with their systems~~ . ~~If~~ **For example, if** such an event were to occur and cause interruptions in our operations **or those of our third-parties on which we rely** , it could result in a material disruption of our drug development programs **and the development of our services and technologies could be delayed** . Any **such** interruption or breach ~~in our systems~~ could adversely affect our business operations and / or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or ~~security~~ **cybersecurity** ~~breach~~ **incident** results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our current and future product candidates could be delayed and our business could be otherwise adversely affected. ~~In addition,~~ **The costs related to significant cybersecurity incidents or disruptions could be material and could exceed the limits of the cybersecurity insurance** we ~~do~~ **maintain against such risks. If the information technology systems of our third- party vendors and other contractors and consultants become subject to disruptions or cybersecurity incidents, we may have insufficient recourse against such third parties and may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Furthermore, significant disruptions of our internal information technology systems or those of our third- party vendors and other contractors and consultants, or cybersecurity incidents could 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), which could result in financial, legal, business, and reputational harm to us. For instance, any such event that leads to unauthorized access to, or use, acquisition, or disclosure of personal information, including personal information regarding our customers, employees or other individuals, could harm our reputation, subject us to liability under and require us to comply with federal and / or state breach notification laws and international law equivalents, domestic or international privacy, data protection, and data security laws such as HIPAA and HITECH, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Such incidents could also result in legal claims or proceedings. Certain cybersecurity incidents require notice to the affected individuals, contractual partners, regulatory authorities such as the Secretary of HHS and attorneys general, and in some cases, require notice to the media. Such notice could harm our reputation and our ability to compete, result in significant legal and financial exposure and reputational damages, and loss of confidence in us, all of which could potentially have an adverse effect on our business. Although we have implemented security measures, there is no guarantee we can protect our data from cybersecurity incidents. Cybersecurity incidents could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, conduct research and development activities, collect, process and prepare company financial information, and manage the administrative aspects of our business. Penalties for violations of these laws vary. For instance, penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include significant civil monetary penalties and, in certain circumstances, criminal penalties with fines up to $ 250, 000 per violation and / or imprisonment. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $ 50, 000 and up to one- year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. 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. 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 ~~separate cyber liability insurance~~ **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. 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. A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID- 19 pandemic, could materially and adversely affect our business. Public health crises such as pandemics or similar outbreaks could adversely impact our business. Previously, our clinical trial operations were directly and indirectly adversely impacted by the COVID- 19 pandemic. A new pandemic or a resurgence of the COVID- 19 pandemic could have adverse economic impacts to us** . We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth. As of March 1, ~~2023~~ **2024** , we had ~~17~~ **16** full- time employees. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, regulatory, sales, marketing, financial and other resources may increase. We

will need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidates to complement our management and employees currently in place and to support our future growth. Future growth would impose significant added responsibilities on members of management, including: • managing our clinical trials effectively; • identifying, recruiting, maintaining, motivating, integrating and retaining additional employees; • managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; • improving our managerial, development, operational, information technology, human resources and finance systems; and • expanding our facilities. If our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate for our company. To that end, we must be able to manage our development efforts and preclinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company. The requirements of being a public company may strain our resources, divert management' s attention and affect our ability to attract and retain qualified board members. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd- Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Compliance with these rules and regulations has increased, and will likely continue to increase, our legal and financial compliance costs, make some activities more difficult, time- consuming or costly, and place significant strain on our personnel, systems and resources. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are 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. This could result in continuing uncertainty regarding compliance matters, higher administrative expenses and a diversion of management' s time and attention. Further, if our compliance efforts differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Being a public company that is subject to these rules and regulations also makes it more expensive for us to obtain and retain director and officer liability insurance, and we may in the future be required to accept reduced coverage or incur substantially higher costs to obtain or retain adequate coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors and qualified executive officers. Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel. We are highly dependent upon our personnel, including Dr. Angelos M. Stergiou M. D., Sc. D. h. c., our President and Chief Executive Officer, and member of our board of directors. Our employment agreement with Dr. Stergiou does not prevent him from terminating his employment with us at any time. The loss of Dr. Stergiou' s services could impede the achievement of our research, development and commercialization objectives. We have not obtained, do not own, nor are we the beneficiary of, key- person life insurance. We employ our executive officers, other than Dr. Stergiou, on an at- will basis and their employment can be terminated by them or us at any time, for any reason and without notice. The loss of any member of our senior management team or the inability to hire or retain experienced senior management personnel could compromise our ability to execute our business plan and harm our operating results. In order to retain valuable employees at our company, in addition to salary and discretionary ~~bonus payments~~ **non- equity incentive plan compensation** , we provide stock options and restricted stock units ~~(~~ **, or** RSUs ~~),~~ that vest over time. The value to our employees of stock options and RSUs could be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies. Our future growth and success ~~depends~~ **depend** not only on our ability to retain, manage and motivate our employees but also on our ability to recruit new employees which is key to our growth. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified talent among biotechnology, pharmaceutical and other businesses. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employment recruitment and retention efforts. Many pharmaceutical and biotechnology companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. Legislation or other changes in U. S. tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service 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 to applicable tax laws and changes are likely to continue to occur in the future. For example, legislation enacted in 2017 informally titled, the Tax Cuts and Jobs Act, or the TCJA, made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 %, the limitation of the tax deduction for net interest expense to 30 % of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses from taxable years beginning after December 31, 2017 to 80 % of current year taxable income and the elimination of net operating loss carrybacks generated in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely) and the modification or repeal of many business deductions and credits. In addition, on March 27, 2020, former President Trump signed into law the " Coronavirus Aid, Relief, and Economic Security Act " or the CARES Act, which included certain changes in tax law intended to stimulate the U. S. economy in light of the COVID- 19 public health emergency, including providing temporary relief from certain aspects of the TCJA that had imposed limitations on the utilization of certain losses, interest expense deductions, and minimum tax credits and provided temporary deferral of certain payroll taxes. 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 shareholders' 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 ability to use net operating losses to offset future taxable income may be subject to limitations. As of December 31, ~~2022~~ **2023**, we had federal and state net operating loss carryforwards of approximately $ ~~49~~ **57**. ~~4~~ **1** million and $ ~~2~~ **3**. 6 million, respectively. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U. S. tax laws, and will begin to expire, if not utilized, beginning in 2027. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, federal NOLs incurred in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited ~~. It is uncertain if and to what extent various states will conform to the Tax Act, or whether any further regulatory changes may be adopted in the future that could minimize its applicability~~. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and certain corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in the ownership of its equity over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes to offset its post- change income may be limited. The Merger constituted an ownership change and as such, our ability to use our NOL carryforwards is materially limited, which may harm our future operating results by effectively increasing our future tax obligations. Risks Related to Ownership of Our Common Stock We will likely need to secure additional capital which may cause dilution to you and our existing stockholders, provide subsequent investors with rights and preference that are senior to yours, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us. We will likely need to raise additional capital in the future. If we raise funds through the issuance of debt or equity, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of a liquidation. In such event, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of common stock. In addition, if we raise funds through the issuance of additional equity, whether through private placements or additional public offerings, such an issuance would dilute our stockholders and, similar to some of our past financings, may contain terms that could result in additional further significant dilution in the future. Debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends, and may require us to grant security interests in our assets, including our intellectual property and for our subsidiaries to guarantee our obligations. The market price and trading volume of shares of our common stock may be volatile. The market price of shares of our common stock has exhibited substantial volatility. Between January 3, ~~2022~~ **2023** and December ~~30~~ **29**, ~~2022~~ **2023**, the daily closing price of shares of our common stock as reported on Nasdaq ranged from a low of $ ~~1~~ **0**. ~~80~~ **88** to a high of $ ~~7~~ **3**. ~~18~~ **86**. The market price of shares of our common stock could continue to fluctuate significantly for many reasons, including the following factors: • reports of the results of our clinical trials regarding the safety or efficacy of our product candidates and surrogate markers; • announcements of regulatory developments or technological innovations by us or our competitors; • announcements of business or strategic transactions or our success in finalizing such a transaction; • announcements of legal or regulatory actions against us or any adverse outcome of any such actions; • changes in our relationships with our licensors, licensees and other strategic partners; • low volume in the number of shares of our common stock traded on Nasdaq; • our quarterly operating results; • announcements of dilutive financing; • announcements of additional potential reverse stock split; • developments in patent or other technology ownership rights; • additional funds may not be available on terms that are favorable to us and, in the case of equity financings, may result in dilution to our stockholders; • government regulation of drug pricing; and • general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine **and Israel and Hamas**. Factors beyond our control may also have an impact on the market price of shares of our common stock. For example, to the extent that other companies within our industry experience declines in their stock prices, the market price of shares of our common stock may decline as well. Inadequate funding for the FDA, the SEC and other domestic and foreign government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA or foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown were to occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business and could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock. Future sales in the public market of shares of our common stock, including shares referred to in the foregoing risk factors or shares issued upon exercise of our outstanding stock options or warrants, or the perception by the market that these sales could occur, could lower

the market price of our common stock or make it difficult for us to raise additional capital. As of December 31, ~~2022~~ **2023**, we had reserved for issuance ~~5~~ **15**, ~~141~~ **853**, ~~053~~ **773** shares of our common stock issuable upon the exercise of outstanding warrants at a weighted- average exercise price of $ ~~5~~ **1**. ~~37~~ **95** per share, 1, ~~039~~ **606**, ~~483~~ **803** shares of our common stock issuable upon the exercise of outstanding stock options at a weighted- average exercise price of $ ~~7~~ **5**. ~~57~~ **92** per share, and ~~255~~ **338**, ~~136~~ **141** shares of our common stock issuable upon the vesting of outstanding restricted stock units with a weighted average grant date fair value of $ ~~3~~ **2**. ~~25~~ **99** per share. Upon exercise or conversion, the underlying shares, similar to those issued as the settlement payment, may be resold into the public market. In the case of outstanding securities that have exercise or conversion prices that are below the market price of our common stock from time to time, our stockholders would experience dilution upon the exercise or conversion of these securities. Certain of our securityholders have registration rights and they can require us, subject to certain limitations, to register their securities for resale and to maintain such registration. Any such resales into the public market could place downward pressure on the price of our common stock. We have issued and may issue additional preferred stock in the future, and the terms of the preferred stock may reduce the value of our common stock. We are authorized to issue up to 5, 000, 000 shares of preferred stock in one or more series. Our board of directors may determine the terms of future preferred stock offerings without further action by our stockholders. If we issue shares of preferred stock, it could affect stockholder rights or reduce the market value of our outstanding common stock. In particular, specific rights granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party. We have settled in the past and may in the future settle legal claims through the issuance of freely tradable shares of our common stock, which results in dilution to holders of our common stock and may adversely affect the market price of our common stock. We have settled in the past and may in the future settle legal claims through the issuance of freely tradable shares of our common stock. We may issue additional shares of common stock as settlement payments in the future. Payment of these amounts in our common stock could cause significant dilution to our stockholders, and the amount of that dilution will vary depending on the price of our common stock at the time of the payment. In addition, the issuance of such a significant number of shares of our **common stock** may cause a decrease in the trading price of our common stock. Anti- takeover provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and provisions of Delaware law could delay or prevent a change of control. Anti- takeover provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws may discourage, delay or prevent a merger or other change of control that stockholders may consider favorable or may impede the ability of the holders of our common stock to change our management and may be constrained by other contractual agreements with third parties. These provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, among other things: • divide our Board of Directors into three classes, with members of each class to be elected for staggered three- year terms; • limit the right of securityholders to remove directors; • prohibit stockholders from acting by written consent; • regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders; and • authorize our Board to issue preferred stock in one or more series, without stockholder approval. In addition, Section 203 of the Delaware General Corporation Law provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15 % of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares for a three- year period following the date on which that person or our affiliate crosses the 15 % stock ownership threshold. Section 203 could operate to delay or prevent a change of control of us. If our common stock becomes subject to the penny stock rules, it may be more difficult to sell our common stock. The SEC has adopted rules that regulate broker- dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $ 5. 00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTC Bulletin Board does not meet such requirements and if the price of our common stock is less than $ 5. 00 and our common stock is no longer listed on a national securities exchange such as Nasdaq, our stock may be deemed a penny stock. The penny stock rules require a broker- dealer, at least two business days prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver to the customer a standardized risk disclosure document containing specified information and to obtain from the customer a signed and date acknowledgment of receipt of that document. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker- dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive: (i) the purchaser' s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares. Our **failure** ~~common stock may be delisted from the Nasdaq Capital Market which could negatively impact the price of our common stock, liquidity and our ability~~ to ~~access~~ **meet** the ~~capital markets. The listing standards of the Nasdaq Capital Market provide that a company, in order to qualify for~~ continued listing ~~, must maintain a minimum stock price of $ 1. 00 and satisfy standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional~~ requirements ~~. If we fail to comply with all listing standards applicable to issuers listed on the Nasdaq Capital Market, our common stock may be delisted. If our common stock is delisted, it could reduce the price~~ of **The** ~~our common stock and the levels of liquidity available to our stockholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital. Delisting from the~~ Nasdaq Capital Market could ~~also~~ result in **a delisting of our common stock. Our shares of common stock are currently listed on The Nasdaq Capital Market. If we fail to satisfy** ~~other~~ -- **the** ~~negative consequences~~

continued listing requirements of Nasdaq , ~~including~~ **such as the corporate governance requirements, minimum bid price requirement or the minimum stockholder' s equity requirement, The Nasdaq Stock Market LLC may take steps to delist our common stock. A delisting of our common stock from The Nasdaq Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in** the potential loss of confidence by **investors,** suppliers, customers and employees ~~, the loss of institutional investor interest~~ and fewer business development opportunities. ~~In the past~~ **On December 6, 2023** , we received a letter from Nasdaq ~~indicating~~ **notifying us** that we ~~did not~~ **no longer** ~~meet~~ **met Nasdaq' s requirements** ~~the minimum bid price of $ 1. 00 per share required~~ for continued listing on ~~the~~ **The** Nasdaq Capital Market ~~pursuant~~ **under Nasdaq Listing Rule 5550 (b) (2), or the MVLS Rule, because, for a period of 30 consecutive business days, the market value of our common stock, calculated based upon the most recent total shares outstanding multiplied by the closing bid price per share, had not maintained a minimum of $ 35. 0 million. In accordance with Nasdaq Listing Rule 5810 (c) (3) (C), we were provided a period of 180 calendar days, or until June 3, 2024, in which** to **regain compliance with the MVLS Rule. To regain compliance, the market value of our common stock must meet or exceed $ 35. 0 million for a minimum of 10 consecutive business days during the 180- day compliance period. If we have not regained compliance with the MVLS Rule by June 3, 2024, Nasdaq will provide notice to us that our securities will be subject to delisting, in which case we may appeal the delisting determination to a Nasdaq Hearings Panel. On March 5, 2024, we received a letter from Nasdaq stating that we have regained compliance under the MVLS Rule by maintaining a market value of our common stock of greater than $ 35 million for 10 consecutive business, and that the matter is now closed. On February 14, 2024, we received a letter from Nasdaq notifying us that we no longer met Nasdaq' s requirements for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550 (a) (2), or** the Minimum Bid Price **Requirement, because, for** ~~Rule. Although we have regained compliance with~~ the ~~Minimum Bid Price Rule after implementing reverse~~ **preceding 30 consecutive business days, our common** stock **did** ~~splits, there can be no~~ **not maintain a** ~~assurance that we will be able to meet the~~ minimum closing bid price **of $ 1. 00 per share. In accordance with Nasdaq Listing** ~~rule~~ **Rule 5810 (c) (3) (A), we were provided a period of 180 calendar days, or until August 12, 2024, to regain compliance with the Minimum Bid Price Requirement. Compliance can be achieved automatically and without further action if the closing bid price of** ~~or~~ **our common stock is at or above $ 1. 00 for a minimum of 10 consecutive business days at any time during the 180- day compliance period, in which case Nasdaq will notify us of our compliance and the matter will be closed. If, however, we do not achieve compliance with the Minimum Bid Price Requirement by August 12, 2024, we may be eligible for additional time to comply. In order to be eligible for such additional time, we will be required to meet the continued listing requirement for market value of publicly held shares and all** other **initial** listing **standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price** ~~requirements~~ **Requirement , and must notify Nasdaq** in **writing of our intention to cure** the ~~future~~ **deficiency during the second compliance period, by effecting a reverse stock split, if necessary. On March 11, 2024, we received a letter from Nasdaq stating that we have regained compliance under the Minimum Bid Price Requirement by maintaining a minimum closing bid price of our common stock of $ 1. 00 per share for 10 consecutive business days, from February 26, 2024 to March 8, 2024, and that the matter is now closed. Our common stock currently remains listed on The Nasdaq Capital Market under the symbol SLS** . We have never declared or paid cash dividends on our common stock and we do not anticipate paying cash dividends on our common stock in the foreseeable future. Our business requires significant funding. We currently plan to invest all available funds and future earnings in the development and growth of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of potential gain for the foreseeable future. ~~101~~ **112**