Risk Factors Comparison 2024-03-15 to 2023-03-31 Form: 10-K

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An investment in our securities involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information about these risks contained in this Annual Report, as well as the other information contained in this Annual Report generally, before deciding to buy our securities. Any of the risks we describe below could adversely affect our business, financial condition, operating results or prospects. The market prices for our securities could decline if one or more of these risks and uncertainties develop into actual events and you could lose all or part of your investment. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in this Annual Report, including our financial statements and the related notes. Summary of Risk ~~Factors~~ **FactorsOur** ~~Our~~ business is subject to a number of risks and uncertainties that you should understand before making an investment decision. These risks include, but are not limited to, the following: Risks Related to our Business ● We have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts or not be able to repay ~~the~~ **certain** ~~Convertible~~ **convertible** ~~Notes~~ **notes** . ● Our losses from operations, negative cash flows, and shareholders ~~'~~**'** deficit as of December 31, ~~2022~~ **2023** ~~as well as a projected potential breach of our cash debt covenant with our debt holder during the 12 month look- forward period from the issuance of the financial statements without taking additional measures, such as raising capital, raises~~ **raise** substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings. ● The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, ~~2022~~ **2023** contains an explanatory paragraph relating to our ability to continue as a going concern. ● If we are unable to develop our product candidates, our ability to generate revenues and viability as a company will be significantly impaired. ● We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all. ● Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays. ● There may be unforeseen challenges in developing our biodefense products. ● We are dependent on government funding, which is inherently uncertain, for the success of our public health business segment operations. ● The terms of our loan and security agreement with Pontifax Medison Finance require, and any future debt financing may require, us to meet certain operating covenants and place restrictions on our operating and financial flexibility. ● If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products. ● If we are not able to maintain or secure agreements with third parties for pre- clinical and clinical trials of our product candidates on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates. ● The manufacturing of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer. ● We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success. **28** ● Even if approved, our products will be subject to extensive post- approval regulation. ● Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market. ● We do not have extensive sales and marketing experience and our lack of experience may restrict our success in commercializing some of our product candidates. ● Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations. ● Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales. ● If we fail to obtain or maintain orphan drug exclusivity for our product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced. ● Federal and / or state health care reform initiatives could negatively affect our business. ● We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products. ● We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient. ● We may use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly. ● We may not be able to compete with our larger and better- financed competitors in the biotechnology industry. ● Competition and technological change may make our product candidates and technologies less attractive or obsolete. ● Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business. ● Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows. ● Adverse developments affecting financial institutions such as actual events or concerns involving liquidity, defaults or non- performance, could adversely affect our operations and liquidity. ● We may not be able to utilize all of our net operating loss carryforwards. ~~29~~ ● Global pathogens could have an impact on financial markets, materials sourcing, patients, governments and population (e. g. COVID- 19). Risks Related to our Intellectual Property ● We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party. ● We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming. **29** ● If we infringe the rights of third parties we could be prevented from selling products, forced to pay

damages, and defend against litigation. Risks Related to **Technology and Intellectual Property ● Our strategy includes an increasing dependence on technology in our operations. If any of our key technology fails, our business could be adversely affected. ● A cybersecurity incident could negatively impact our business and our relationships with our employees, service providers, patients, clinical study sites and government agencies. Risks Related to** our Securities ● The price of our common stock may be highly volatile. ● If we fail to ~~remain current with our~~ **meet Nasdaq' s** listing requirements, we could be removed from The Nasdaq Capital Market, which would limit the ability of broker- dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market **and negatively impact our ability to raise capital** . ● Shareholders may suffer substantial dilution related to issued stock warrants, options and convertible notes. ● Our shares of common stock are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares **. ● Our common stock is deemed to be a " penny stock, " which may make it more difficult for investors to sell their shares due to suitability requirements** . ● We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock. ● Upon our dissolution, our stockholders may not recoup all or any portion of their investment. ● The issuance of our common stock pursuant to the terms of the asset purchase agreement with Hy Biopharma may cause dilution and the issuance of such shares of common stock, or the perception that such issuances may occur, could cause the price of our common stock to fall. **● Repayment of certain convertible notes, if they are not otherwise converted, will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on our indebtedness. ● The issuance of shares of common stock upon conversion of certain convertible notes could substantially dilute shareholders' investments and could impede our ability to obtain additional financing. ● Our Board of Directors can, without stockholder approval, cause preferred stock to be issued on terms that adversely affect holders of our common stock.** Risks Related to our BusinessWe have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts. We have experienced significant losses since inception and, at December 31, ~~2022~~ **2023** , had an accumulated deficit of approximately $ ~~219~~ **225** . ~~6~~ **7** million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, ~~2022~~ **2023** , we had approximately $ ~~13~~ **8** . 4 million in cash and cash equivalents available, and as of March ~~24~~ **8** , ~~2023~~ **2024** we had approximately $ ~~10~~ **7** . ~~4~~ **5** million in cash and cash equivalents available. ~~Based~~ **Without additional funding, 30based** on our projected budgetary needs ~~,~~ **and** funding from existing contracts and grants over the next year ~~and sales pursuant to our At Market Issuance Sales Agreement (" B. Riley Sales Agreement ") with B. Riley Securities, Inc. (" B. Riley ")~~ , we expect to be able to maintain the current level of our operations into the ~~third~~ **fourth** quarter of ~~2023~~ **2024** . In September 2014, we entered into a contract with the NIH for the development of RiVax ® to protect against exposure to ricin toxin that would provide up to $ 24. 7 million of funding in the aggregate over six years if options to extend the contract are exercised by the NIH. In 2017, we were awarded two separate grants from the NIH of approximately $ 1. 5 million each to support our pivotal Phase 3 trials of HyBryte ™ for the treatment of CTCL and SGX942 for the treatment of oral mucositis in head and neck cancer. In December 2020, we were awarded Direct to Phase II SBIR grant from NIAID of approximately $ 1. 5 million to support manufacture, formulation (including thermostabilization) and characterization of COVID- 19 and EVD vaccine candidates in conjunction with the CoVaccine HT ™ adjuvant. Our biodefense grants have an overhead component ~~30that~~ -- **that** allows us an agency- approved percentage over our incurred costs. We estimate that the overhead component associated with our existing contracts and grants will fund some fixed costs for direct employees working on these contracts and grants as well as other administrative costs. As of December 31, ~~2022~~ **2023** , we had approximately $ **844, 000** ~~1. 7 million~~ in awarded grant funding available. Our product candidates are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of these product candidates. From inception through December 31, ~~2022~~ **2023** , we have expended approximately $ ~~116~~ **119** million developing our current product candidates for pre- clinical research and development and clinical trials. We currently expect to spend approximately $ ~~3~~ **5** . ~~7~~ **5** million for the year ending December 31, ~~2023~~ **2024** in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements, of which approximately $ 0. ~~7~~ **3** million is expected to be reimbursed through our existing government ~~contracts and~~ grants. We have no control over the resources and funding ~~NIH, BARDA and NIAID~~ **U. S. government agencies** may devote to our programs, which may be subject to periodic renewal and which generally may be terminated by the government at any time for convenience. Any significant reductions in the funding of U. S. government agencies or in the funding areas targeted by our business could materially and adversely affect our biodefense program and our results of operations and financial condition. If we fail to satisfy our obligations under the government contracts, the applicable Federal Acquisition Regulations allow the government to terminate the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the government any incomplete work. If ~~NIH, BARDA or NIAID~~ **U. S. government agencies** do not exercise future funding options under the contracts or grants, terminate the funding or fail to perform their responsibilities under the agreements or grants, it could materially impact our biodefense program and our financial results. Unless and until we are able to generate sales or licensing revenue from one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations. If we cannot raise such additional funds, we may have to delay or stop some or all of our drug development programs. Our losses from operations, negative cash flows, and shareholders' deficit as of December 31, ~~2022~~ **2023** ~~as well as a projected potential breach of our cash debt covenant with our debt holder during the 12 month look- forward period from the~~

~~issuance of the financial statements without taking additional measures, such as raising capital, raises~~ **raise** substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings. We have concluded that substantial doubt exists about our ability to continue as a going concern for the 12 months following the issuance of the financial statements included in this Annual Report on Form 10- K. As of December 31, ~~2022~~ **2023**, we had cash and cash equivalents of **approximately** $ ~~13~~ **8**. ~~6~~ **4** million and current liabilities of **approximately** $ ~~16~~ **6**. ~~5~~ **2** million. As of the issuance date of these financial statements, we believe that we have sufficient resources available to support our development activities and business operations and timely satisfy our obligations as they come due into the ~~third~~ **fourth** quarter of ~~2023~~ **2024**. We do not have sufficient cash and cash equivalents as of the date of filing this Annual Report on Form 10- K to support our operations for at least the 12 months following the issuance of the financial statements. To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to secure additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations, securing additional proceeds from government contract and grant programs, ~~securing additional proceeds available from the sale of shares of our common stock via the B. Riley Sales Agreement with B. Riley~~ and potentially amending the loan agreement with Pontifax **Medison Finance** to reduce the conversion price in ~~order~~ **31order** to allow for conversion of a portion of the debt which will reduce our **liabilities** ~~accounts payable~~; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, identify and enter into any strategic transactions that will provide the capital that we will require or achieve the other strategies to alleviate the conditions that raise substantial doubt about our ability to continue as a going concern. If none of these alternatives are available, or if available, are not available on satisfactory terms, we will not have sufficient cash resources and liquidity to fund our business operations for at least the 12 months following the date the financial statements are issued. The failure to obtain sufficient capital on acceptable terms ~~31when~~ **when** needed may require us to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives and our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, ~~2022~~ **2023** contains an explanatory paragraph relating to our ability to continue as a going concern. The auditor' s opinion on our audited financial statements for the year ended December 31, ~~2022~~ **2023** includes an explanatory paragraph stating that we have incurred recurring losses from operations that raise substantial doubt about our ability to continue as a going concern. While we believe that we will be able to obtain the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our development efforts. Accordingly, our business, prospects, financial condition, and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. If we are unable to develop our product candidates, our ability to generate revenues and viability as a company will be significantly impaired. In order to generate revenues and profits, our organization must, along with corporate partners and collaborators, positively research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and pre- clinical development and will require significant further funding, research, development, pre- clinical and / or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates: ● we may not be able to maintain our current research and development schedules; ● we may be unable to secure procurement contracts on beneficial economic terms or at all from the U. S. government or others for our biodefense products; ● we may encounter problems in clinical trials; or ● the technology or product may be found to be ineffective or unsafe, or may fail to obtain marketing approval. If any of the risks set forth above occur, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may be unable to develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of any other technology we develop, even if it is shown to be effective, if: ● it is not economical or the market for the product does not develop or diminishes; ● we are not able to enter into arrangements or collaborations to manufacture and / or market the product; **32** ● the product is not eligible for third- party reimbursement from government or private insurers; ● others hold proprietary rights that preclude us from commercializing the product; ● we are not able to manufacture the product reliably; ● others have brought to market similar or superior products; ~~or32~~ **or** ● the product has undesirable or unintended side effects that prevent or limit its commercial use. We expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance. We are a late- stage biopharmaceutical company. Our operations to date have been primarily limited to developing our technology and undertaking pre- clinical studies and clinical trials of our product candidates in our two active business segments, Specialized BioTherapeutics and Public Health Solutions. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter- to- quarter or year- to- year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described

elsewhere in this Annual Report and also include: ● our ability to obtain additional funding to develop our product candidates; ● our ability to repay existing debt in accordance with its terms; ● delays in the commencement, enrollment and timing of clinical trials; ● the success of our product candidates through all phases of clinical development; ● any delays in regulatory review and approval of product candidates in clinical development; ● our ability to obtain and maintain regulatory approval for our product candidates in the U. S. and foreign jurisdictions; ● potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market; ● our dependence on third- party contract manufacturing organizations to supply or manufacture our products; ● our dependence on contract research organizations to conduct our clinical trials; ● our ability to establish or maintain collaborations, licensing or other arrangements; ● market acceptance of our product candidates; ● our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations; ● competition from existing products or new products that may emerge; ● the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products; ● our ability to discover and develop additional product candidates; **33** ● our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business; ● our ability to attract and retain key personnel to manage our business effectively; ● our ability to build our finance infrastructure and improve our accounting systems and controls; ● potential product liability claims; ~~33~~ ● potential liabilities associated with hazardous materials; and ● our ability to obtain and maintain adequate insurance policies. Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance. We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all. To date, we have no approved product on the market and have not generated any significant product revenues. We have funded our operations primarily from sales of our securities and from government contracts and grants. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential or successfully obtain government procurement or stockpiling agreements. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability. Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays. Our business is subject to very stringent federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change. The regulatory process applicable to our products requires pre- clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years, is uncertain as to outcome, and requires the expenditure of substantial capital and other resources. We estimate that the clinical trials of our product candidates that we have planned will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Favorable results in early studies or trials, if any, may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing, Phase 1 and Phase 2 clinical trials does not ensure that later Phase 2 or Phase 3 clinical trials will be successful. In addition, we, the FDA or other regulatory authorities may suspend clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or the FDA or other regulatory authorities find deficiencies in our submissions or conduct of our trials. We may not be able to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product (for example, the FDA may not recognize fast track designation upon an NDA submission, resulting in no priority review and subjecting us to longer potential review times than originally anticipated). Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed. Following any regulatory approval, a marketed product and its manufacturer are subject to continual regulatory review. Later discovery of problems with a product or manufacturer may result in restrictions on such product or manufacturer. These restrictions may include product recalls and suspension or withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export, among other things, of a product are subject to extensive regulation by ~~governmental~~ **34governmental** authorities in the U. S. and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and / or criminal prosecution. There may be unforeseen challenges in developing our biodefense products. For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans, referred to as the Animal Rule. However, we will still have to establish that the vaccines we are ~~34developing~~ - - **developing** are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the Animal Rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time- consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasures for bioterrorism agents. Despite the Animal Rule,

the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post- marketing studies, and could be restricted in use in only certain populations. The government' s biodefense priorities can change, which could adversely affect the commercial opportunity for the products we are developing. Further, other countries have not, at this time, established criteria for review and approval of these types of products outside their normal review process, i. e., there is no Animal Rule equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data. Additionally, few facilities in the U. S. and internationally have the capability to test animals with ricin, or otherwise assist us in qualifying the requisite animal models. We have to compete with other biodefense companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct the testing in a predictable timeframe or at all. We are dependent on government funding, which is inherently uncertain, for the success of our biodefense operations. We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U. S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U. S. government policies resulting from various political and military developments. Our receipt of government funding is also dependent on our ability to adhere to the terms and provisions of the original grant and contract documents and other regulations. We can provide no assurance that we will receive or continue to receive funding for grants and contracts we have been awarded. The loss of government funds could have a material adverse effect on our ability to progress our biodefense business. The terms of our loan and security agreement with Pontifax Medison Finance require, and any future debt financing may require, us to meet certain operating covenants and place restrictions on our operating and financial flexibility. In December 2020, we entered into a loan and security agreement with Pontifax Medison Finance (the " Loan and Security Agreement "), that is secured by a lien covering substantially all of our assets, other than our intellectual property and licenses for intellectual property. The Loan and Security Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to protect and maintain our intellectual property and comply with all applicable laws, deliver certain financial reports, ~~maintain a minimum cash balance~~ and maintain insurance coverage. Negative covenants include, among others, covenants restricting us from transferring any material portion of our assets, incurring additional indebtedness, engaging in mergers or acquisitions, changing foreign subsidiary voting rights, repurchasing shares, paying dividends or making other distributions, making certain investments, and creating other liens ~~on~~ **35on** our assets, including our intellectual property, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. If we default under the terms of the Loan and Security Agreement or any future debt facility, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender' s right to repayment would be senior to the rights of the holders of our common stock. The lender could declare a default upon the occurrence of any event that it interprets as a material adverse effect as defined under the Loan and Security Agreement or based upon ~~35our~~ -- **our** insolvency. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If the parties we depend on for supplying our drug substance raw materials and certain manufacturing- related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products. We do not have or anticipate having internal manufacturing capabilities. We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing- related services to produce material that meets appropriate content, quality and stability standards, which material will be used in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to be able to develop, produce, secure regulatory approval of and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities. We rely on third parties for pre- clinical and clinical trials of our product candidates and, in some cases, to maintain regulatory files for our product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates. We rely on academic institutions, hospitals, clinics and other third- party collaborators for preclinical and clinical trials of our product candidates. Although we monitor, support, and / or oversee our pre- clinical and clinical trials, because we do not conduct these trials ourselves, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these

third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then preclinical and / or clinical trials of our product candidates may be extended, delayed or terminated, or our data may be rejected by the FDA or regulatory agencies. The manufacturing of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer. The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with current Good Manufacturing Practice (" cGMP ") or similar requirements that the FDA or foreign regulators establish. We, or our materials suppliers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able ~~to~~ **36to** maintain compliance with the FDA' s cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products. ~~36We~~ **We** may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and human resources, we are currently focusing on the regulatory approval of certain product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on existing and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in an area in which it would have been more advantageous to enter into a partnering arrangement. Even if approved, our products will be subject to extensive post- approval regulation. Once a product is approved, numerous post- approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. Depending on the circumstances, failure to meet these post- approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre- marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval. Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market. Even if the FDA approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid. Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug product; cost-effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare payers; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any. The degree of market acceptance of any product that we develop will depend on a number of factors, including: ● cost-effectiveness; ● the safety and effectiveness of our products, including any significant potential side effects, as compared to alternative products or treatment methods; ● the timing of market entry as compared to competitive products; ● the rate of adoption of our products by doctors and nurses; **37** ● product labeling or product insert required by the FDA for each of our products; ● reimbursement policies of government and third- party payors; ~~37~~ ● effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and ● unfavorable publicity concerning our products or any similar products. Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by major pharmaceutical companies, biotechnology companies and manufacturers of generic drugs. Our products may also compete with new products currently under development by others. Physicians, patients, third- party payors and the medical community may not accept and utilize any of our product candidates. If our products do not achieve market acceptance, we will not be able to generate significant revenues or become profitable. Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and could require us to seek additional financing. We do not have extensive sales and marketing experience and our lack of experience may restrict our success in commercializing some of our product candidates. We do not have extensive experience in marketing or selling pharmaceutical products whether in the U. S. or internationally. To obtain the expertise necessary to successfully market and sell any of our products, the development of our own commercial infrastructure and / or collaborative commercial arrangements and partnerships will be required. Our ability to make that investment and also execute our current operating plan is dependent

on numerous factors, including, the performance of third party collaborators with whom we may contract. Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations. Initiatives to reduce the federal deficit and to change health care delivery are increasing cost- containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third- party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services. Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales. Serious adverse events or undesirable side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials may show that our product candidates cause serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities. ~~If~~ **38If** any of our product candidates cause serious adverse events or undesirable side effects: ● regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product; ~~38~~ ● regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies; ● we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; ● we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product; ● we may be required to limit the patients who can receive the product; ● we may be subject to limitations on how we promote the product; ● sales of the product may decrease significantly; ● regulatory authorities may require us to take our approved product off the market; ● we may be subject to litigation or product liability claims; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products. If we fail to obtain or maintain orphan drug exclusivity for our product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200, 000 in the U. S., or a patient population greater than 200, 000 in the U. S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U. S. In the EU, the European Medicines Agency' s Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life- threatening or chronically debilitating condition affecting not more than five in 10, 000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life- threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. In the U. S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user- fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. ~~Even~~ **39Even** though we have orphan drug designation for HyBryte ™ in the U. S. and Europe, and ~~SGX203,~~ RiVax ® in the U. S., we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing drugs or biologic products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Absent patent or other intellectual property protection, even after an orphan drug is approved, the FDA or European Medicines Agency may subsequently approve the same drug with the same active moiety ~~39for~~ -- **for** the same condition if the FDA or European Medicines Agency concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Federal and / or state health care reform initiatives could negatively affect our business. The availability of reimbursement by governmental and other third- party payers affects the market for any pharmaceutical product. These third- party payers continually attempt to contain or reduce the costs of healthcare. There have been a number of legislative and regulatory proposals to change the healthcare system and further proposals are likely. Medicare' s policies may decrease the market for our products. Significant uncertainty exists with respect to

the reimbursement status of newly approved healthcare products. Third- party payers are increasingly challenging the price and cost- effectiveness of medical products and services. Once approved, we might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations. On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug / labs that were separately billed at that time. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment. In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. We expect that there will continue to be a number of U. S. federal and state proposals to implement governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability. We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products. We currently rely on license agreements from New York University, Yeda Research and Development Company Ltd., the University of Texas Southwestern Medical Center, the University of British Columbia, and George B. McDonald, MD as well as sublicense agreement from VitriVax for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, if at all. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates. See " Business – Patents and Other Proprietary Rights " for a description of our license agreements. Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to: ● the scope of rights granted under the license agreement and other interpretation- related issues; ● the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; ● the sublicensing of patent and other rights; **40** ● our diligence obligations under the license agreement and what activities satisfy those diligence obligations; ● the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; ~~and40~~ -- **and** ● the priority of invention of patented technology. If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Additionally, the research resulting in certain of our licensed patent rights and technology was funded by the U. S. government. As a result, the government may have certain rights, or march- in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non- exclusive license authorizing the government to use the invention for non- commercial purposes. The government can exercise its march- in rights if it determines that action is necessary because we fail to achieve practical application of the government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U. S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the U. S. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract or partner with outside researchers, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are successfully developed and approved for commercialization, then we will need to enter into additional collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and / or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights may limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third- party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products. Additionally, if we do not enter into relationships with additional third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force or enter into commercialization agreements with other companies. Development of an effective sales force in any part of the world would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved. We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient. The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with aggregate limits of liability of $ 10 million, which may not be sufficient to cover our potential liabilities. Because

liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity. ~~We 41~~**We** may use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly. Our research and development processes and / or those of our third party contractors involve the controlled use of hazardous materials and chemicals. These hazardous chemicals are reagents and solvents typically found in a chemistry laboratory. Our operations also may produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. While we attempt to comply with all environmental laws and regulations, including those relating to the outsourcing of the disposal of all hazardous chemicals and waste ~~41products~~ -- **products**, we cannot eliminate the risk of contamination from or discharge of hazardous materials and any resultant injury. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. Compliance with environmental laws and regulations may be expensive. Current or future environmental regulations may impair our research, development or production efforts. We might have to pay civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. We are not insured against these environmental risks. We may agree to indemnify our collaborators in some circumstances against damages and other liabilities arising out of development activities or products produced in connection with these collaborations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations. We may not be able to compete with our larger and better financed competitors in the biotechnology industry. The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Most of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in the therapeutic area of inflammatory bowel diseases. We face intense competition in the biodefense area from various public and private companies and universities as well as governmental agencies, such as the U. S. Army, which may have their own proprietary technologies that may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to compete with our existing and future competitors, which could lead to the failure of our business. Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non- patent exclusivity and / or the listing with the FDA by the competitor of patents covering its newly- approved drug product. Periods of non- patent exclusivity for new versions of existing drugs such as our current product candidates can extend up to three and one-half years. See " Business – The Drug Approval Process. " These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits. Competition and technological change may make our product candidates and technologies less attractive or obsolete. We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than us, obtaining FDA approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products. ~~There 42~~**There** can be no assurance that any of our product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept our product (s) as a treatment of choice. ~~42Furthermore~~ -- **Furthermore**, the pharmaceutical research industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA regulations preclude us from forecasting revenues or income with certainty or even confidence. Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business. We currently have 15 employees and we depend upon these employees, in particular Dr. Christopher Schaber, our President and Chief Executive Officer, to manage the day- to- day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. We may be unable to effectively manage and operate our business, and our business may suffer, if we lose the services of our employees. Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows. During recent years, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by current and future economic conditions. These conditions could have an adverse effect on our industry and business, including our financial condition, results of operations, and cash flows. To the extent that we

do not generate sufficient cash from operations, we may need to issue stock or incur indebtedness to finance our plans for growth. Recent turmoil in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through borrowings, under either existing or newly created instruments in the public or private markets on terms we believe to be reasonable, if at all. Adverse developments affecting financial institutions such as actual events or concerns involving liquidity, defaults or non- performance, could adversely affect our operations and liquidity. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (" SVB ") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the " FDIC ") as receiver. Despite subsequent actions taken by the U. S. Department of the Treasury, the U. S. Federal Reserve and the FDIC to ensure that all depositors of SVB had access to all of their cash deposits following the closure of SVB, uncertainty and liquidity concerns in the broader financial services industry remain. We maintain cash balances at a third- party financial institution in excess of the FDIC insurance limit. Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired to the extent the financial institution with which we maintain cash balances faces liquidity constraints or failures. Any material decline in our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in significant disruptions to our business, any of which could have material adverse impacts on our operations and liquidity. There is no guarantee that the U. S. Department of Treasury, the U. S. Federal Reserve and the FDIC will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all. We may not be able to utilize all of our net operating loss carryforwards. The State of New Jersey' s Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused net operating loss (" NOL ") carryforwards to other New Jersey- based corporate taxpayers. We ~~sold 43~~**sold 2022, 2021 and** 2020 ~~and 2019~~ New Jersey NOL carryforwards, resulting in the recognition of $ 1, **767, 803 and $ 1,** 154, 935 ~~and $ 864, 742~~ of income tax benefit, net of transaction costs during the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively ~~. We sold our 2021 New Jersey NOL carryforwards and received $ 1, 161, 197, net of transaction costs, in January 2023, which will be recognized in the first quarter of 2023~~. We have not yet sold our ~~2022~~ **2023** New Jersey NOL carryforwards but may do so in the future. If there is an unfavorable change in the State of New Jersey' s Technology Business Tax Certificate Program (whether as a result of a change in law, policy or otherwise) that terminates the program or eliminates or reduces our ability to use or sell our ~~43NOL~~ -- **NOL** carryforwards or if we are unable to find a suitable buyer to utilize our New Jersey NOL carryforwards to the extent the NOLs expire before we are able to utilize them against our taxable income, our cash taxes may increase which may have an adverse effect on our financial condition. Global pathogens that could have an impact on financial markets, materials sourcing, patients, governments and population (e. g. COVID- 19). ~~Based on the current outbreak of the Coronavirus~~ **Global pathogens (e. g.,** SARS- CoV- 2, the pathogen responsible for COVID- 19 **) could cause** ~~, which has already had~~ an impact on financial markets **and therefore** ~~, there could be additional~~ repercussions to our operating business, including but not limited to, the sourcing of materials for our product candidates, manufacture of supplies for our preclinical and / or clinical studies, delays in clinical operations, which may include the availability or the continued availability of patients for our trials due to such things as quarantines, our conduct of patient monitoring and clinical trial data retrieval at investigational study sites. The ~~future impact~~ **impacts** of ~~the outbreak~~ **outbreaks** ~~is~~ **are** highly uncertain and cannot be predicted, and we cannot provide any assurance that ~~the~~ **any** outbreak will not have a material adverse impact on our operations or future results or filings with regulatory health authorities. The extent of the impact to us, if any, will depend on future developments, including actions taken to contain the ~~coronavirus~~ **pathogen**. Risks Related to our Intellectual PropertyWe may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party. Our near and long- term prospects depend in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor. Although we and our licensors have filed various patent applications covering the uses of our product candidates, patents may not be issued from the patent applications already filed or from applications that we might file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and has been the subject of much litigation. Any patents we own or license, now or in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the U. S. Patent and Trademark Office (the " PTO ") regarding the breadth of claims allowed in biotechnology patents. In addition, because patent applications in the U. S. are maintained in secrecy until patent applications publish or patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The PTO may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents. It is also possible that our owned and licensed technologies may infringe on patents or other rights owned by others, and licenses to which may not be available to us. We may be unable to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay

licensing fees or cease activities altogether because of patent rights of third parties. ~~In~~ **44In** addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor. ~~44We~~ **We** may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming. The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO proceedings, and related legal and administrative proceedings are costly and time- consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know- how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all. Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly. Also, a third party may assert that our patents are invalid and / or unenforceable. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation could result in inadequate protection for our product candidates and / or reduce the value of any license agreements we have with third parties. Interference proceedings brought before the PTO may be necessary to determine priority of invention with respect to our patents or patent applications. During an interference proceeding, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference proceeding may result in substantial costs and distraction to our management. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the price of our common stock could be adversely affected. If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and / or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources. 45Risks Related to **Technology and Intellectual PropertyOur strategy includes an increasing dependence on technology in our operations. If any of our key technology fails, our business could be adversely affected. Our operations are increasingly dependent on technology. Our information technology systems are critical to our ability to develop our products and otherwise operating our business. Problems with the operation of the information or communication technology systems we use could adversely affect, or temporarily disable, all or a portion of our operations. Further, any systems failures could impede our ability to timely collect and report financial results in accordance with applicable laws. A cybersecurity incident could negatively impact our business and our relationships with our employees, service providers, patients, clinical study sites and government agencies. We use information technology and operational technology assets, including computer and information networks, in substantially all aspects of our business operations. We also use mobile devices, social networking and other online activities to connect with our employees, service providers, patients, clinical study sites and government agencies. Such uses give rise to cybersecurity risks, including security breach, espionage, system disruption, theft and inadvertent release of information. Our business involves the storage and transmission of numerous classes of sensitive and / or confidential information and intellectual property, including clinical trial participants' personal information, private information about employees and financial and strategic information about us and our business partners. If we fail to assess and identify cybersecurity threats, we may become increasingly vulnerable to such threats. Additionally, while we have implemented measures to prevent security breaches and cyber incidents, our preventive measures and incident response efforts may not be entirely effective. Also, the regulatory environment surrounding information security and privacy is increasingly demanding, with the frequent imposition of new and constantly changing requirements. This changing regulatory landscape may cause increasingly complex compliance challenges, which may increase our compliance costs. Any failure to comply with these changing security and privacy laws and regulations could result in significant penalties, fines, legal challenges and reputational harm. The theft, destruction, loss, misappropriation, or**

release of sensitive and / or confidential information or intellectual property, or interference with our information technology systems or the technology systems of third parties on which we rely, could result in business disruption, negative publicity, brand damage, violation of privacy laws, loss of confidence, potential liability and competitive disadvantage. Risks Related to our SecuritiesThe price of our common stock may be highly volatile. The market price of our securities, like that of many other research and development public pharmaceutical and biotechnology companies, has been highly volatile and the price of our common stock may be volatile in the future due to a wide variety of factors, including: ● announcements by us or others of results of pre- clinical testing and clinical trials; ● announcements of technological innovations, more important bio- threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors; ● failure of our common stock to continue to be listed or quoted on a national exchange or market system, such as ~~The~~ Nasdaq **or the New York** Stock **Exchange** ~~Market (" Nasdaq ") or NYSE Amex LLC~~; ● our quarterly operating results and performance; ● developments or disputes concerning patents or other proprietary rights; ● mergers or acquisitions; ● litigation and government proceedings; **46** ● adverse legislation; ● changes in government regulations; ● our available working capital; ● economic and other external factors; and ● general market conditions. Since January 1, ~~2022~~ **2023**, the closing stock price of our common stock has fluctuated between a high of $ ~~15~~ **7**. ~~00~~ **65** per share to a low of $ ~~5~~ **0**. ~~70~~ **40** per share. On March ~~24~~ **8**, ~~2023~~ **2024**, the last reported ~~sales~~ **sale** ~~prices~~ **price** of our common stock on The Nasdaq Capital Market was $ ~~1~~ **0**. ~~84~~ **77** per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock and warrants by us, as well as potential sale of common stock by the holders of warrants ~~and~~ **,** options **and convertible promissory notes**, could have an adverse effect on the market price of our shares. If we fail to ~~remain current with our~~ **meet Nasdaq' s** listing requirements, we could be removed from The Nasdaq Capital Market, which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market **and negatively impact our ability to raise capital**. Companies trading on ~~The~~ Nasdaq ~~Stock Market~~, such as our Company, must be reporting issuers under Section 12 of the Exchange Act ~~, as amended~~, and must meet the listing requirements in order to maintain the listing of common stock on The Nasdaq Capital Market. If we do not meet these requirements, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker- dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market. On ~~December 20~~ **June 23**, ~~2021~~ **2023**, we received a **letter** ~~written notice (the " Bid Price Notice ")~~ from the Listing Qualifications ~~department~~ **Department** of Nasdaq ~~indicating~~ **stating** that we were not in compliance with the $ 1. 00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550 (a) (2) for continued listing on the Nasdaq Capital Market (the " Minimum Bid Price ~~Requirement~~ **Rule** ") **because** ~~. The notification of noncompliance had no immediate effect on the listing or trading of~~ our common stock ~~on~~ **failed to maintain a minimum closing bid price of $ 1. 00 for 30 consecutive trading days. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we were afforded an initial period of 180 calendar days, or until December 20, 2023, to regain compliance with the Minimum Bid Price Rule. We were unable to regain compliance with the Minimum Bid Price Rule prior to the expiration of the 180 calendar day period. On December 21, 2023, we received written notice from Nasdaq stating that we had not complied with the Minimum Bid Price Rule and were not eligible for a second 180- day period because we did not comply with the $ 5, 000, 000 minimum stockholders' equity initial listing requirement for** The Nasdaq Capital Market. ~~46On June 21~~ **In that regard**, **our Quarterly Report on Form 10- Q** ~~2022, we delivered to the Listing Qualifications Department of Nasdaq a confidential plan to regain compliance with the Minimum Bid Price Requirement, which included upcoming important milestones such as the submission of new drug application~~ for ~~HyBryte ™ in~~ the **quarter ended September 30** ~~treatment of cutaneous T- cell lymphoma and the initiation of a Phase 2 psoriasis clinical trial. On June 22~~, ~~2022~~ **2023 reported stockholders** ~~, the Listing Qualifications Department of Nasdaq sent us a second notice, indicating that we were eligible for an additional 180 period, or until December 19, 2022, in which to regain compliance. Additionally, on November 16, 2022, Nasdaq notified us that we no longer complied with the continued listing requirement to maintain a minimum of $ 2, 500, 000 in shareholders~~' equity ~~nor did we meet the alternatives~~ of **$ 4** ~~market value of listed securities or net income from continuing operations (the " Shareholders' Equity Requirement "). We were unable to regain compliance with the Minimum Bid Price Requirement prior to the expiration of the second 180 calendar day period. On December 20~~, ~~2022~~ **221**, ~~we received written~~ **155. As a result, the** notice ~~(the " Notice ") from Nasdaq stating that we had not complied with the Minimum Bid Price Requirement or the Shareholders' Equity Requirement. The Notice~~ indicated that our common stock would be suspended from trading on Nasdaq unless we requested a hearing before a hearings panel by December ~~27~~ **28**, ~~2022~~ **2023**. ~~We timely requested~~ **Nasdaq has scheduled** a hearing **for March 26, 2024**, which stayed any trading suspension of our common stock until completion of the Nasdaq hearing process and expiration of any additional extension period granted by the panel following the hearing. ~~In advance of the hearing,~~ **There can be no assurance that** we **will be able** ~~provided the Nasdaq Hearings Panel (the " Panel ") with our plan~~ to regain ~~compliance. The appeal was heard by the Panel on February 2, 2023. At a special meeting of stockholders held on February 8, 2023, our stockholders granted our Board of Directors the discretion to effect a reverse stock split of our common stock through an amendment to our Second Amended and Restated Certificate of Incorporation at a ratio of not less than 1- for- 2 and not more than 1- for- 20, with such ratio to be determined by our Board of Directors. We effected a reverse stock split of our common stock at a ratio of 1 post- split share for every 15 pre- split shares on Thursday, February 9, 2023. Our common stock continued to be traded on The Nasdaq Capital Market under the symbol SNGX and began trading on a split- adjusted basis when the market opened on Friday, February 10, 2023. On February 21, 2023, we received a letter (the " Continued Listing Letter ") from Nasdaq, stating that the Panel granted our request to continue listing on Nasdaq, on the condition that (1) on February 24, 2023, we shall have demonstrated~~ compliance with the Minimum Bid Price **Rule** ~~Requirement, by evidencing a closing bid price of $ 1. 00 or more per share for a minimum of ten consecutive trading sessions; and (2) on or before March 31, 2023, we shall demonstrate compliance with the Shareholders' Equity Requirement. As of the close of the market on February 24, 2023, we~~

~~satisfied the first condition – compliance with the Minimum Bid Price Requirement for a minimum of ten consecutive trading sessions. We have requested an extension of the time by which we must regain compliance with the Shareholders' Equity Requirement. There can be no assurance that we will be able to regain compliance with the Shareholders' Equity Requirement~~ prior to **the hearing date** ~~any extended deadline established by Nasdaq~~ or at all, that Nasdaq will grant us an extension of time to achieve ~~such~~ compliance **with the Minimum Bid Price Rule** or that our common stock will remain listed on The Nasdaq Capital Market. **If the hearing does not result in Nasdaq granting us an extension of time to achieve compliance with the Minimum Bid Price Rule, our common stock will be delisted from Nasdaq. If our common stock is delisted from Nasdaq, it will have material negative impact on the actual and potential liquidity of our securities, as well as material negative impact on our ability to raise future capital. If, for any reason, Nasdaq should delist our common stock from trading on its exchange and we are unable to obtain listing on another national securities exchange 47or take action to restore our compliance with the Nasdaq continued listing requirements, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our shareholders: ● the liquidity of our common stock; ● the market price of our common stock; ● our ability to obtain financing for the continuation of our operations; ● the number of institutional and general investors that will consider investing in our securities; ● the number of market makers in our common stock; ● the availability of information concerning the trading prices and volume of our common stock; and ● the number of broker- dealers willing to execute trades in shares of our common stock.** Shareholders may suffer substantial dilution related to issued stock warrants, options and convertible notes. As of December 31, ~~2022~~ **2023**, we had a number of agreements or obligations that may result in dilution to investors. These include: ● warrants to purchase a total of approximately ~~667~~ **6, 538, 073** shares of our common stock at a current weighted average exercise price of $ ~~29~~ **1**. ~~25~~ **50**; ● options to purchase approximately ~~192~~ **906**, ~~273~~ **892** shares of our common stock at a current weighted average exercise price of $ ~~27~~ **5**. **73** ~~56; ● the B. Riley Sales Agreement pursuant to which we may, but have no obligation to, sell up to an additional $ 26. 6 million worth of our common stock as of March 24, 2023, subject to the limitations imposed by General Instruction I. B. 6 to Form S- 3~~; and ● convertible promissory notes issued to Pontifax Medison Finance, **of** which ~~may be~~ **there was $ 3, 000, 000 of principal and $ 63, 351 of accrued interest outstanding. The Convertible Notes were** ~~converted~~ **convertible at (i) 90 %** ~~into up to 162, 602 shares~~ of **the closing price of our** common stock **on the day before the delivery of the conversion notice with respect to the first 588, 599 shares issuable upon conversion** at ~~a price of~~ **December 31, 2023 and (ii)** $ ~~61~~ **1**. ~~50 per~~ **70 with respect to all** ~~share~~ **shares** ~~under the initial loan borrowing~~ **issuable upon conversion in excess** of ~~$ 10 million~~ **the first 588, 599 shares issued upon conversion at December 31, 2023**. ~~47We~~ **We** also have an incentive compensation plan for our management, employees and consultants. We have granted, and expect to grant in the future, options to purchase shares of our common stock to our directors, employees and consultants. To the extent that warrants ~~or~~ **,** options **or convertible promissory notes** are exercised **or converted**, our stockholders will experience dilution and our stock price may decrease. Additionally, the sale, or even the possibility of the sale, of the shares of common stock underlying these warrants ~~and~~ **,** options **and convertible promissory notes** could have an adverse effect on the market price for our securities or on our ability to obtain future financing. Our shares of common stock are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares. Our common stock has from time to time been " thinly- traded, " meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non- existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk- averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non- existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a ~~broader~~ **48broader** or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained **. Our common stock is deemed to be a " penny stock, " which may make it more difficult for investors to sell their shares due to suitability requirements. Our common stock is subject to Rule 15g- 1 through 15g- 9 under the Exchange Act, which imposes certain sales practice requirements on broker- dealers which sell our common stock to persons other than established customers and " accredited investors " (generally, individuals with a net worth in excess of $ 1, 000, 000 or annual incomes exceeding $ 200, 000 (or $ 300, 000 together with their spouses)). For transactions covered by this rule, a broker- dealer must make a special suitability determination for the purchaser and have received the purchaser' s written consent to the transaction prior to the sale. This rule adversely affects the ability of broker- dealers to sell our common stock and the ability of our stockholders to sell their shares of common stock. Additionally, our common stock is subject to SEC regulations for " penny stock. " The regulations require that prior to any non- exempt buy / sell transaction in a penny stock, a disclosure schedule set forth by the SEC relating to the penny stock market must be delivered to the purchaser of such penny stock. This disclosure must include the amount of commissions payable to both the broker- dealer and the registered representative and current price quotations for the common stock. The regulations also require that monthly statements be sent to holders of penny stock that disclose recent price information for the penny stock and information of the limited market for penny stocks. These requirements may adversely affect the market liquidity of our common stock**. We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock. We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, our stockholders must rely on sales of their common stock after price

appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares. Upon our dissolution, our stockholders may not recoup all or any portion of their investment. In the event of our liquidation, dissolution or winding- up, whether voluntary or involuntary, the proceeds and / or our assets remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed to the holders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding- up. In this event, our stockholders could lose some or all of their investment. The issuance of our common stock pursuant to the terms of the asset purchase agreement with Hy Biopharma Inc. may cause dilution and the issuance of such shares of common stock, or the perception that such issuances may occur, could cause the price of our common stock to fall. On April 1, 2014, we entered into an option agreement pursuant to which Hy Biopharma granted us an option to purchase certain assets, properties and rights (the " Hypericin Assets ") related to the development of Hy Biopharma' s synthetic hypericin product candidate for the treatment of CTCL, which we refer to as HyBryte ™, from Hy Biopharma. In exchange for the option, we paid $ 50, 000 in cash and issued 288 shares of common stock in the aggregate to Hy Biopharma and its assignees. We subsequently exercised the option, and on September 3, 2014, we entered into an asset purchase agreement **(the " Asset Purchase Agreement ")** with Hy Biopharma, pursuant to which we purchased the Hypericin Assets. Pursuant to the **Asset** ~~purchase~~ **Purchase** ~~agreement~~ **Agreement**, we initially paid $ 275, 000 in cash and issued 12, 328 shares of common stock in the aggregate to Hy Biopharma and its assignees, and the licensors of the license agreement acquired from Hy Biopharma. Also, on September 3, 2014, we entered into a Registration Rights Agreement with Hy Biopharma, pursuant to which we may be required to file a registration statement with the SEC. In March 2020, we issued 130, 413 shares of common stock at a value of $ 5, 000, 000 (based upon an effective per share price of $ 38. 40 as a result of HyBryte ™ demonstrating statistically significant treatment response in the Phase 3 clinical trial. We will be required to issue up to $ 5. 0 ~~million~~ **49million** worth of our common stock (subject to a cap equal ~~48to~~ **to** 19. 9 % of our issued and outstanding common stock) in the aggregate, if HyBryte ™ is approved for the treatment of CTCL by either the FDA or the EMA. The number of shares that we may issue under the **Asset** ~~purchase~~ **Purchase** ~~agreement~~ **Agreement** will fluctuate based on the market price of our common stock. Depending on market liquidity at the time, the issuance of such shares may cause the trading price of our common stock to fall. We may ultimately issue all, some or none of the additional shares of our common stock that may be issued pursuant to the **Asset** ~~purchase~~ **Purchase** ~~agreement~~ **Agreement**. We are required to register any shares issued pursuant to the purchase agreement for resale under the Securities Act of 1933, as amended (the " Securities Act "). After any such shares are registered, the holders will be able to sell all, some or none of those shares. Therefore, issuances by us under the purchase agreement could result in substantial dilution to the interests of other holders of our common stock. Additionally, the issuance of a substantial number of shares of our common stock pursuant to the **Asset** ~~purchase~~ **Purchase** ~~agreement~~ **Agreement**, or the anticipation of such issuances, could make it more difficult for us to sell equity or equity- related securities in the future at a time and at a price that we might otherwise wish to effect sales. Repayment of certain convertible notes, if they are not otherwise converted, will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on our indebtedness. Our ability to pay the principal of and / or interest on the convertible notes issued pursuant to the Loan and Security Agreement with Pontifax Medison Finance (the " Convertible Notes ") depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service the Convertible Notes or other future indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt and implement one or more alternatives, such as selling assets, restructuring indebtedness or obtaining additional debt financing or equity financing on terms that may be onerous or highly dilutive. Our ability to refinance the Convertible Notes or other future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the Convertible Notes. The issuance of shares of common stock upon conversion of the Convertible Notes could substantially dilute shareholders' investments and could impede our ability to obtain additional financing. The Convertible Notes are convertible into shares of our common stock and give the holders an opportunity to profit from a rise in the market price of our common stock such that conversion or exercise thereof could result in dilution of the equity interests of our shareholders. **As of March 8, 2024, there was $ 2, 900, 858 of principal and $ 45, 840 of accrued interest outstanding under the Convertible Notes.** We have no control over whether the holders will exercise their right to convert their Convertible Notes. While the Convertible Notes are convertible at ~~a minimum~~ **(i) 90 % of the closing** price of **our common stock on the day before the delivery of the conversion notice with respect to the first 442, 400 shares issuable upon conversion as of March 8, 2024 and (ii)** $ ~~61~~ **1**. ~~50 per~~ **70 with respect to all** ~~share~~ **shares** ~~which is higher than our current market price~~ **issuable upon conversion in excess of the first 442, 400 shares issued upon conversion as of March 8, 2024**, we cannot predict the market price of our common stock at any future date, and therefore, cannot predict whether the Convertible Notes will be converted. We ~~may~~ also **may** choose to reduce the conversion price of the Convertible Notes ~~in order to reduce our accounts payable~~, which would likely cause the Convertible Notes to be ~~convertible~~ --- **converted** into a significant amount of our common stock **and reduce our liabilities**. The existence and potentially dilutive impact of the Convertible Notes may prevent us from obtaining additional financing in the future on acceptable terms, or at all. Our Board of Directors can, without stockholder approval, cause preferred stock to be issued on terms that adversely affect holders of our common stock. Under our Certificate of Incorporation, our Board of Directors is authorized to issue up to 230, 000 shares of preferred stock, of which none are issued and outstanding as of the date of this prospectus. Also, our Board of Directors, without stockholder approval, may determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares. If our Board of Directors causes shares of preferred stock to be issued, the rights of the holders of our common stock would likely be

subordinate to those of preferred holders and therefore could be adversely affected. Our Board of Directors' ability to determine the terms of preferred stock and to cause its issuance, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire a majority of our outstanding common stock. Preferred shares issued by our Board of Directors could include voting **50** ~~rights or super voting rights, which could shift the ability to control the Company to the holders of the preferred stock. Preferred stock could also have conversion rights into shares of our common stock at a discount to the market price of our common stock, which could negatively affect the market for our common stock. In addition, preferred stock would have 49~~