Risk Factors Comparison 2024-09-27 to 2023-10-13 Form: 10-K

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Our business is subject to numerous risks and uncertainties that you should consider before investing in our common stock. Some of the principal risk factors that make an investment in the Company speculative or risky are summarized as follows: ● Our company is in the developmental stage and has no products approved for commercial sale, no generated revenue, and may never achieve profitability. ● The Company will need to raise substantial additional capital in the future to fund operations. ● Due to the nature of the process involved in the development process of pharmaceuticals, the Company can provide no assurance of the successful and timely development of new drugs. ● The Company must comply with significant and complex government regulations, which may delay or prevent the commercialization of drug candidates. ~~Page 52 of 95~~ ● The Company can provide no assurance that drug candidates will obtain regulatory approval or that the results of clinical studies will be favorable. ● In the event that regulatory approvals are obtained, drug candidates will be subject to regulatory review. Failing to comply with U. S. and foreign regulations could result in loss of approvals to market such drugs and would harm the business. ● Development of drug candidates requires significant research and development, which will lead to significant research and development costs. ● The Company will be unable to proceed with its business plan without obtaining additional financing. ● The Company has limited experience in conducting or supervising clinical trials and must outsource clinical trials. Additionally, we lack suitable facilities for clinical testing which leads to a reliance on third parties. ● The Company may be unable to attract or retain and motivate skilled personnel which will delay product development programs and research and development efforts. **Page 59 of 106** ● The Company has no sales or marketing personnel. ● The Company' s collaborative relationships with third parties could cause the Company to expend significant resources and incur substantial business risk with no assurance of financial return. ● The Company may be liable for damages caused by biological and hazardous material. ● The Company depends on senior management and their loss or unavailability could put the Company at a competitive disadvantage. ● There exist conflicts of interest among officers, directors and stockholders. ● Risks relating to dependence on U. S. government contracts. ● Company common stock may be considered " penny stock ". ● Management of the Company has identified a material weakness in internal controls that if not remediated could result in material misstatements in our financial statements. These and other material risks we face are described more fully herein which investors should carefully review prior to making an investment decision with respect to the Company or its securities. Risks Specific to Our BusinessOur company is a development stage company that has no products approved for commercial sale, never generated any revenues and may never achieve revenues or profitability. Our company is a development stage company that has no products approved for commercial sale, never generated any revenues and may never achieve revenues or profitability. Our ability to generate revenue depends heavily on: ● demonstration and proof of principle in pre- clinical trials that a nanoviricide is safe and effective; ● successful development of our first product candidate in our pipeline; ● our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking; ~~Page 53 of 95~~ ● the successful commercialization of our product candidates; and ● market acceptance of our products. All of our existing product candidates are in early stages of development. It will be several years, if ever, until we have a commercial drug product available for resale. If we do not successfully develop and commercialize these products, we will not achieve revenues or profitability in the foreseeable future, if at all. If we are unable to generate revenues or achieve profitability, we may be unable to continue our operations. We are a clinical drug development stage company with a limited operating history, making it difficult for you to evaluate our business and your investment. Our proposed products are subject to all of the risks inherent in the establishment of a new business enterprise, including but not limited to: ● the absence of an operating history; ● the lack of commercialized products; **Page 60 of 106** ● insufficient capital; ● expected substantial and continual losses for the foreseeable future; ● limited experience in dealing with regulatory issues; the lack of manufacturing experience and limited marketing experience; ● an expected reliance on third parties for the development and commercialization of our proposed products; ● a competitive environment characterized by numerous, well- established and well capitalized competitors; ● reliance on key personnel. Because we are subject to these risks, you may have a difficult time evaluating our business and your investment in our company. Our ability to become profitable depends primarily on the following factors: ● our ability to develop drugs, obtain approval for such drugs, and if approved, to successfully commercialize our nanoviricide drug (s); ● our R & D efforts, including the timing and cost of clinical trials; and ● our ability to enter into favorable alliances with third parties who can provide substantial capabilities in clinical development, regulatory affairs, sales, marketing and distribution. Even if we successfully develop and market our drug candidates, we may not generate sufficient or sustainable revenue to achieve or sustain profitability. We have incurred significant operating losses and may not ever be profitable. As of June 30, ~~2023~~ **2024** , we had a cash and cash equivalent balance of $ ~~8~~ **4** , ~~149~~ **797** , ~~808~~ **778** . Also, we have incurred significant operating losses since its inception, resulting in an accumulated deficit of $ ~~131~~ **139** , ~~080~~ **374** , ~~749~~ **895** at June 30, ~~2023~~ **2024** . Such losses are expected to continue for the foreseeable future. **We** ~~Page 54 of 95We~~ will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms. **Management** ~~While we believe~~ **believes** ~~we have~~ **that the Company' s cash and cash equivalents balance of approximately $ 4. 8 million, additional capital raised of approximately $ 1. 5 million by ATM sales of our common stock from July 1, 2024 through September 10, 2024, and the Company' s existing resources, including availability under its $ 3 million line of credit will not be** sufficient ~~cash~~ to ~~be able to take our NV~~ **fund the Company' s planned operations and expenditures for at least 12 months from the date of the filing of this Form 10** - **K. As a result substantial doubt exists about** ~~CoV- 2 drug candidates, into initial human clinical trials, we currently do not have sufficient resources to complete~~

the **Company' s ability to continue as a going concern** ~~development, clinical trials, and commercialization of any of our proposed products~~ . Management is actively exploring additional required funding through non- dilutive grants and contracts, partnering, debt or equity financing pursuant to its plan. There is no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us to fund continuing operations. **We** ~~Management believes that as a result of the management plan, our existing resources and access to the capital markets will permit us to fund planned operations and expenditures. However, we~~ cannot provide assurance that ~~its~~ **the Company' s** plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. In the event that we cannot obtain acceptable financing, or that we are unable to secure additional financing on acceptable terms, we would be unable to complete development of our various drug candidates. This would necessitate implementing staff reductions and operational adjustments that would include reductions in the following business areas: ● research and development programs; ● preclinical studies and clinical trials; material characterization studies, regulatory processes; **Page 61 of 106** ● a search for third party marketing partners to market our products for us. The amount of capital we may need will depend on many factors, including the: ● progress, timing and scope of our research and development programs; ● progress, timing and scope of our preclinical studies and clinical trials; ● time and cost necessary to obtain regulatory approvals; ● time and cost necessary to establish our own marketing capabilities or to seek marketing partners; ● time and cost necessary to respond to technological and market developments; ● changes made or new developments in our existing collaborative, licensing and other commercial relationships; and ● new collaborative, licensing and other commercial relationships that we may establish. Our fixed expenses, such as real estate taxes and facility and equipment maintenance, rent, and other contractual commitments, may increase in the future, as we may: ● enter into leases for new facilities and capital equipment; ● enter into additional licenses and collaborative agreements; and ● incur additional expenses associated with being a public company. We have limited experience in drug development, and may not be able to successfully develop any drugs. Our ability to achieve revenues and profitability in our business will depend, among other things, on our ability to: ● develop products internally or obtain rights to them from others on favorable terms; ~~Page 55 of 95~~ ● complete laboratory testing and human studies; ● obtain and maintain necessary intellectual property rights to our products; ● successfully complete regulatory review to obtain requisite governmental agency approvals; ● enter into arrangements with third parties to manufacture our products on our behalf; and ● enter into arrangements with third parties to provide sales and marketing functions. **Page 62 of** ~~Development~~ **106Development** of pharmaceutical products is a time- consuming process, subject to a number of factors, many of which are outside of our control. Consequently, we can provide no assurance of the successful and timely development of new drugs. Our drug candidates are in their clinical and pre-clinical developmental stages. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into reliable, commercially competitive drugs on a timely basis. Drugs that we may develop are not likely to be commercially available for several years. The proposed development schedules for our drug candidates may be affected by a variety of factors, including technological difficulties, proprietary technology of others, and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our drug candidates could result either in such drugs being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long- term nature of our projects, the unproven technology involved and the other factors described elsewhere in " Risk Factors ", we may not be able to complete successfully the development or marketing of any drugs. We may fail to successfully develop and commercialize our drug candidates if they: ● are found to be unsafe or ineffective or fail to meet the appropriate endpoints in clinical trials; ● do not receive necessary approval from the FDA or foreign regulatory agencies; ● fail to conform to a changing standard of care for the diseases they seek to treat; or ● are less effective or more expensive than current or alternative treatment methods. Drug development failure can occur at any stage of clinical trials and as a result of many factors and there can be no assurance that we or our collaborators will reach our anticipated clinical targets. Even if we or our collaborators complete our clinical trials, we do not know what the long- term effects of exposure to our drug candidates will be. Furthermore, our drug candidates may be used in combination with other treatments and there can be no assurance that such use will not lead to unique safety issues. Failure to complete clinical trials or to prove that our drug candidates are safe and effective would have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations. We have limited manufacturing expertise and we may have to rely on external manufacturers. We believe that the technology we use to manufacture our products and compounds is proprietary, although some of the generalities are patented or patent- pending. For our products, we may have to disclose all necessary aspects of this technology to contract manufacturers to enable them to manufacture the products and compounds for us. We plan to have discussions with manufacturers under non- disclosure and non- compete agreements that are intended to restrict them from using or revealing this technology, but we cannot be certain that these manufacturers will comply with these restrictions. In addition, these manufacturers could develop their own technology related to the work they perform for us that we may need to manufacture our products or compounds. We could be required to enter into an agreement with that manufacturer if we wanted to use that technology ourselves or allow another manufacturer to use that technology. The manufacturer could refuse to allow us to use their technology or could demand terms to use their technology that are not acceptable. **We** ~~Page 56 of 95We~~ must comply with significant and complex government regulations, compliance with which may delay or prevent the commercialization of our drug candidates. The R & D, manufacture and marketing of drug candidates are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, R & D activities (including testing in primates and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing. Noncompliance with applicable requirements can result in various adverse consequences, including approval delays or refusals to approve drug licenses or other

applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, recalls or seizures of products, injunctions against shipping drugs and total or partial suspension of production and / or refusal to allow a company to enter into governmental supply contracts. ~~The~~ **Page 63 of 106The** process of obtaining FDA approval has historically been costly and time consuming. Current FDA requirements for a new human drug or biological product to be marketed in the United States include: (1) the successful conclusion of pre- clinical laboratory and animal tests, if appropriate, to gain preliminary information on the product' s safety; (2) filing with the FDA of an IND application to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well- controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a New Drug Application, or NDA, for a drug product or a biological license application, or BLA, for a biological product to allow commercial distribution of the drug or biologic. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our drug candidates through clinical testing and to market. The FDA reviews the results of the clinical trials and may order the temporary or permanent discontinuation of clinical trials at any time if it believes the drug candidate exposes clinical subjects to an unacceptable health risk. Investigational drugs used in clinical studies must be produced in compliance with current good manufacturing practice, or GMP, rules pursuant to FDA regulations. Sales outside the United States of products that we develop will also be subject to regulatory requirements governing human clinical trials and marketing for drugs and biological products and devices. The requirements vary widely from country to country, but typically the registration and approval process takes several years and requires significant resources. In most cases, even if the FDA has not approved a product for sale in the United States, the product may be exported to any country if it complies with the laws of that country and has valid marketing authorization by the appropriate authority. There are specific FDA regulations that govern this process. We also are subject to the following risks and obligations, related to the approval of our products: ● The FDA or foreign regulators may interpret data from pre- clinical testing and clinical trials in different ways than we interpret them. ● If regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution. ● In addition, many foreign countries control pricing and coverage under their respective national social security systems. ● The FDA or foreign regulators may not approve our manufacturing processes or manufacturing facilities. ● The FDA or foreign regulators may change their approval policies or adopt new regulations. ● Even if regulatory approval for any product is obtained, the marketing license will be subject to continual review, and newly discovered or developed safety or effectiveness data may result in suspension or revocation of the marketing license. ● If regulatory approval of the product candidate is granted, the marketing of that product would be subject to adverse event reporting requirements and a general prohibition against promoting products for unapproved or " off- label " uses. ● In some foreign countries, we may be subject to official release requirements that require each batch of the product we produce to be officially released by regulatory authorities prior to its distribution by us. ~~Page 57 of 95~~ ● We will be subject to continual regulatory review and periodic inspection and approval of manufacturing modifications, including compliance with current GMP regulations. ~~We~~ **Page 64 of 106We** can provide no assurance that our drug candidates will obtain regulatory approval or that the results of clinical studies will be favorable. The testing, marketing and manufacturing of any product for use in the United States will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. Preclinical and clinical trials may reveal that one or more products are ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed drug and failure to receive such approvals would have an adverse effect on the drug' s potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a proposed drug may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such proposed drug from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist. Preclinical and clinical studies of our product candidates may not be successful. If we are unable to generate successful results from preclinical and clinical studies of our product candidates, or experience significant delays in doing so, our business may be materially harmed. We have no products on the market and except NV- CoV- 2 (NV- 387) which is in Phase ~~1a~~ **Ia** / ~~1b~~ **Ib** clinical trials, all of our other product candidates are in preclinical development. In particular, none of our product candidates, other than NV- CoV- 2 (NV- 387), have ever been tested in a human subject. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and, if approved, successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety, purity and potency of our product candidates. The success of our product candidates will depend on several factors, including the following: ● successfully designing preclinical studies which may be predictive of clinical outcomes; ● successful results from preclinical and clinical studies; ● receipt of marketing approvals from applicable regulatory authorities; ● obtaining and maintaining patent and trade secret protection for future product candidates; ● establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and ● successfully commercializing our products, if and when approved, whether alone or in collaboration with others. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete the development or commercialization of our product candidates, which would materially harm our business. Page ~~58~~ **65** of ~~95Because~~ **106Because** the results of preclinical testing are not necessarily predictive of future results, our products may not have favorable results in our planned clinical trials. Even if we have positive results from our preclinical testing of our products, this may not necessarily be predictive

of the results from our planned clinical trials in humans. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. If we fail to produce positive results in our clinical trials, the development timeline and regulatory approval and commercialization prospects for our products, and, correspondingly, our business and financial prospects, would be materially adversely affected. Even if we obtain regulatory approvals, our marketed drug candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U. S. and foreign regulations, we could lose our approvals to market these drugs and our business would be seriously harmed. Following any initial regulatory approval of any drugs we may develop, we will also be subject to continuing regulatory review, including the review of adverse experiences and clinical results that are reported after our drug candidates are made commercially available. This would include results from any post- marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. The discovery of any previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug or manufacturer or facility, including withdrawal of the drug from the market. If we are required to withdraw all or more of our drugs from the market, we may be unable to continue revenue- generating operations. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured drugs ourselves, including reliance on the third- party manufacturer for regulatory compliance. Our drug promotion and advertising is also subject to regulatory requirements and continuing FDA review. Development of our drug candidates requires a significant investment in R & D. Our R & D expenses in turn, are subject to variation based on a number of factors, many of which are outside of our control. A sudden or significant increase in our R & D expenses could materially and adversely impact our results of operations. Our R & D cost estimates and budgets are based on discussions with industry professionals and service providers. These may not take into account all of the activities involved for the development. Additionally, regulatory requirements may change from time to time and may dictate additional activities that lead to increased expenditures beyond budgeted. Because we expect to expend substantial resources on R & D, our success depends in large part on the results as well as the costs of our R & D. A failure in our R & D efforts or substantial increase in our R & D expenses would adversely affect our results of operations. R & D expenditures are uncertain and subject to much fluctuation. Factors affecting our R & D expenses include, but are not limited to: ● the number and outcome of clinical studies we are planning to conduct; for example, our R & D expenses may increase based on the number of late- stage clinical studies that we may be required to conduct; ● the number, extent, and outcome of pre- clinical studies we are planning to conduct; for example, our R & D expenses may increase based on the number and extent of IND- enabling pre-clinical studies including CMC Studies, Tox Package Studies, and Quality Programs that we may be required to conduct; ● the number of drugs entering into pre- clinical development from research; for example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision; ● licensing activities, including the timing and amount of related development funding or milestone payments; for example, we may enter into agreements requiring us to pay a significant up- front fee for the purchase of in- process R & D that we may record as R & D expense; andPage ~~59~~ **66** of ~~95~~ **106** ● maintenance of our relationship with our licensing partner TheraCour and our rights and obligations under the license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy payment obligations under such agreement, our ability to develop and commercialize the affected product candidate may be adversely affected. Any loss of our rights under our license agreements could delay or completely terminate our product development efforts for the affected product candidate. We will be unable to proceed with our business plan without obtaining additional financing to support our budgeted Clinical Development, Pre- Clinical Research and Development and other costs. We believe we have sufficient funds on hand to ~~take one drug candidate into initial human~~ **complete the remaining tasks of the Phase I** clinical ~~trials~~ **trial and obtain a completed clinical study report, and to develop and file a Phase II clinical trial application to evaluate use of NV- 387 for the treatment of RSV infection** . We have estimated a total cash expenditure budget of approximately $ 7. ~~1~~ **9** million for the period of July ~~2023~~ **2024** through October ~~2024~~ **2025** of which approximately $ 4. ~~1~~ **9** million is expected to be spent on research and development for our drug candidates, including **completion and reporting of** the ~~human~~ **Phase I** clinical ~~trials~~ **trial and preparation for the Phase II clinical trial** of our lead drug candidate NV- **387** ~~CoV- 2~~ for treatment of **RSV** ~~coronavirus diseases~~, an IND filing for RSV indication, and approximately $ 3 million is budgeted for general and administrative expenses. We are aware of numerous products under development or manufactured by competitors that are used for the prevention or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that potentially directly compete with our drug candidates even though their approach to such treatment is different. We hope that our drug candidates under development and in clinical trials will address major markets within the anti- viral sector. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of the market introduction of some of our potential drugs or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop drugs, complete pre- clinical testing, clinical trials, approval processes and supply commercial quantities to market are important competitive factors. We expect that competition among drugs approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent protection. The successful development of biopharmaceuticals is highly uncertain. A variety of factors including, pre- clinical study results or regulatory approvals, could cause us to abandon development of our drug candidates. Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in the early phases of development may fail to reach the market for several reasons including: ● pre-clinical study results that may show the product to be less effective than desired (e. g., a clinical trial fails to meet its primary

objectives) or to have harmful or problematic side effects; ● failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or an IND and later NDA, preparation, discussions with the FDA, an FDA request for additional pre- clinical or clinical data or unexpected safety or manufacturing issues; ● manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economical; and ● the proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized. Success in pre- clinical and early clinical studies does not ensure that large- scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product to the next, and may be difficult to predict. Page ~~60~~ **67** of ~~95We~~ **106We** have limited experience in conducting or supervising clinical trials and must outsource all clinical trials. We have limited experience in conducting or supervising clinical trials that must be performed to obtain data to submit in concert with applications for approval by the FDA. The regulatory process to obtain approval for drugs for commercial sale involves numerous steps. Drugs are subjected to clinical trials that allow development of case studies to examine safety, efficacy, and other issues to ensure that sale of drugs meets the requirements set forth by various governmental agencies, including the FDA. In the event that our protocols do not meet standards set forth by the FDA, or that our data is not sufficient to allow such trials to validate our drugs in the face of such examination, we might not be able to meet the requirements that allow our drugs to be approved for sale. Because we have limited experience in conducting or supervising clinical trials, we plan to continue to outsource our clinical trials to third parties. We have no control over their compliance with procedures and protocols used to complete clinical trials in accordance with standards required by the agencies that approve drugs for sale. If these subcontractors fail to meet these standards, the validation of our drugs would be adversely affected, causing a delay in our ability to meet revenue- generating operations. We are subject to risks inherent in conducting clinical trials. The risk of non- compliance with FDA- approved good clinical practices by clinical investigators, clinical sites, or data management services could delay or prevent us from developing or ever commercializing our drug candidates. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA- approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize our drug candidates. We or regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the patients enrolled in our clinical trials. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials. Our clinical trial operations will be subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions that we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our drug candidates or we may be criminally prosecuted. If we are unable to complete clinical trials and have our products approved due to our failure to comply with regulatory requirements, we will be unable to commence revenue-generating operations. **Page 68 of** ~~Efforts~~ **106Efforts** of government and third- party payers to contain or reduce the costs of health care may adversely affect our revenues even if we were to develop an FDA approved drug. Our ability to earn sufficient returns on our drug candidates may depend in part on the extent to which government health administration authorities, private health coverage insurers and other organizations will provide reimbursement for the costs of such drugs and related treatments. Significant uncertainty exists as to the reimbursement status of newly approved health care drugs, and we do not know whether adequate third- party coverage will be available for our drug candidates. If our current and proposed drugs are not considered cost- effective, reimbursement to the consumers may not be available or sufficient to allow us to sell drugs on a competitive basis. The failure of the government and third- party payers to provide adequate coverage and reimbursement rates for our drug candidates could adversely affect the market acceptance of our drug candidates, our competitive position and our financial ~~performancePage~~ **performanceWe** ~~61 of 95We~~ will rely upon licensed patents to protect our technology. We may be unable to obtain or protect such intellectual property rights, and we may be liable for infringing upon the intellectual property rights of others. Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others for which we have entered into licensing agreements. We have exclusive licenses from TheraCour to novel technologies, proprietary technologies, and knowhow, some of which has been filed in patent applications, and we expect to file patents of our own in the coming years. There can be no assurance that any of these patent applications will ultimately result in the issuance of a patent with respect to the technology owned by us or licensed to us. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the United States Patent and Trademark Office use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of

claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. Further, we rely on a combination of trade secrets, know- how, technology and nondisclosure, and other contractual agreements and technical measures to protect our rights in the technology. If any trade secret, know- how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected. We do not believe that any of the drug candidates we are currently developing infringe upon the rights of any third parties nor are they infringed upon by third parties; however, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our drug candidates so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed from the TheraCour Pharma. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors. Moreover, the cost to us of any litigation or other proceeding relating to technology we license and other intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management' s efforts. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations. Other companies or organizations may assert patent rights that prevent us from developing and commercializing our drug candidates. We are in a relatively new scientific field that has generated many different patent applications from organizations and individuals seeking to obtain important patents in the field. Because the field is so new, very few of these patent applications have been fully processed by government patent offices around the world, and there is a great deal of uncertainty about which patents will issue, when, to whom, and with what claims. It is possible that there will be significant litigation and other proceedings, such as interference proceedings in various patent offices, relating to patent rights in the field. Others may attempt to invalidate TheraCour' s patents or other intellectual property rights. Even if our rights are not directly challenged, disputes among third parties could lead to the weakening or invalidation of those intellectual property rights. ~~Thus~~ **Page 69 of 106Thus** , it is possible that one or more organizations will hold patent rights to which we will need a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non- exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and drug candidates, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. **We** ~~Page 62 of 95We~~ are dependent upon TheraCour for the rights to develop the products we intend to sell and our license agreements with TheraCour require that TheraCour is the sole developer and supplier of our licensed products. Our ability to develop, manufacture and sell the products the Company plans to develop is derived from our licensing agreements with TheraCour. The Agreements may be terminated by TheraCour as a result of: the insolvency or bankruptcy proceedings by or against the Company, a general assignment by the Company to its creditors, the dissolution of the Company, cessation by the Company of business operations for ninety (90) days or more or the commencement by the Company or an affiliate to challenge or invalidate the issued patents. The Company does not hold the rights to any other patents nor does the Company conduct its own research and development to develop other products to manufacture and sell. In addition, TheraCour is the sole developer of our licensed products and we are required to pay TheraCour fees for indirect and direct costs incurred by TheraCour for its licensed products. Therefore, we are dependent upon TheraCour for all of our product development needs. If the Company' s Agreement with TheraCour is terminated, it is unlikely we will be able to commence revenue- generating operations or that the Company could continue operating at all. The expiration or loss of patent protection may adversely affect our future revenues and operating earnings. We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, research and of our product candidates. In particular, patent protection is important in the development and eventual commercialization of our products and product candidates. Patents covering our products and product candidates normally provide market exclusivity, which is important in order for our products and product candidates to become profitable. Certain of the patents, which comprise the intellectual property that we license, expire between 2026 and 2028. While we believe the patent holders may seek additional patent coverage that may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan and we currently do not have any products for sale. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and product candidates, we may be open to competition from generic versions of such methods and devices. We lack suitable facilities for clinical testing; and rely on third parties. The Company does not have facilities that could be used to conduct clinical testing. We expect to contract with third parties to conduct all clinical testing required to obtain approvals for any drugs that we might develop. We currently outsource all testing to a number of third parties in various collaborations and service contracts. Any of our collaborators or service providers may discontinue the service contract or collaboration. If this were to occur, then we would be required to modify our priorities and goals, obtain other collaborators or service providers to replace the ones we lose, or we may even be forced to abandon certain drug development programs. In addition, any failures by third parties to adequately perform their responsibilities may delay the submission of our proposed products for regulatory approval, impair our ability to deliver our products on a timely basis, increase our costs, or otherwise impair our competitive position. ~~We~~

Page 70 of 106We have limited manufacturing experience. We have not previously manufactured products in the highly regulated environment of pharmaceutical manufacturing. There are numerous regulations and requirements that must be maintained to obtain licensure and the permits required to commence manufacturing, as well as additional requirements to continue manufacturing pharmaceutical products. We own facilities that we use to manufacture clinical quantities of any products that might be developed by us. We believe that this cGMP- capable facility may allow us to produce limited quantities of a drug after approval for initial market entry, and that such an effort may make commercial sense if the treatment course requirements and afflicted patient populations are limited, and if the remuneration for the treatment course is appropriate. However, we do not own, nor lease facilities suitable for cGMP manufacture of any of our drug candidates in large commercial quantities, nor do we have the resources at this time to acquire or lease suitable facilities. At present, we have not retained any contract manufacturing organizations (CMO) for commercial manufacture or for clinical product manufacture. **We** ~~Page 63 of 95We~~ may be unable to attract, retain, and motivate skilled personnel which will delay our product development programs and our research and development efforts. Our success depends on our continued ability to attract, retain, and motivate highly qualified scientific personnel who must undergo extensive training to assist in our research programs. Competition for skilled and qualified personnel and academic and other research collaborations is intense. If we lose the services of personnel with the necessary skills, or if there are extensive delays in training such personnel, it could significantly impede the achievement of our research and development objectives. We are currently experiencing extreme staffing constraints as well as financing constraints that have already caused substantial delays and may continue to cause further delays in our estimated timelines, unless we are successful at raising additional funds and at attracting and retaining highly skilled employees with specific skill- sets. There can be no assurance that we will be able to raise sufficient funding or that even if we are able to raise funding on terms favorable to the Company, that we will be able to hire and retain such qualified employees, The inability to hire and retain these employees will significantly delay our objectives including filing an IND with the FDA. We have no sales and marketing personnel. We are an early stage development company with limited resources. We do not currently have any products available for sale, and have not secured sales and marketing staff at this early stage of operations. We cannot generate sales without a sales or marketing staff and we cannot guarantee we will be successful in developing one. Even if we were to successfully develop approvable drugs, we will not be able to sell these drugs if we or our third- party manufacturers fail to comply with manufacturing regulations. Since we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates. We cannot commercialize any of our product candidates to generate revenue until the appropriate regulatory authorities have reviewed and approved the marketing applications for the product candidates. We cannot ensure that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate that we or our collaborators develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Regulatory approval processes outside the United States include all of the risks associated with the FDA approval process. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. We license our core technology from TheraCour and we are dependent upon them as they have exclusive development rights. If we lose the right to utilize any of the proprietary information that is the subject of this license agreement, we may incur substantial delays and costs in development of our drug candidatesWe have entered into Material License Agreements with TheraCour. TheraCour has exclusive rights to develop exclusively for us, the materials that comprise the core drugs of our planned business. TheraCour is a development stage company with limited financial resources and needs the Company' s progress payments to further the development of the nanoviricides. We control the research and work TheraCour performs on our behalf and no costs may be incurred without our prior authorization or approval. ~~We~~ **Page 71 of 106We** depend on TheraCour and other third parties to perform manufacturing activities effectively and on a timely basis. If these third parties fail to perform as required, this could impair our ability to deliver our products on a timely basis or cause delays in our clinical trials and applications for regulatory approval, and these events could harm our competitive position and adversely affect our ability to commence revenue- generating operations. The manufacturing process for pharmaceutical products is highly regulated, and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We, and our manufacturers are subject to the FDA' s current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards and similar regulations are in effect in other countries. In addition, our manufacturing operations are subject to routine inspections by regulatory agencies. ~~Page 64 of 95Our~~ -- **Our** collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return. We anticipate substantial reliance upon strategic collaborations for marketing and the commercialization of our drug candidates and we may rely even more on strategic collaborations for R & D of our other drug candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering our drug candidates for non-medical applications to government agencies does not require us to develop new sales, marketing or distribution capabilities beyond those already existing in the company. Selling antiviral drugs, however, does require such development. We plan to sell antiviral drugs through strategic partnerships with pharmaceutical companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited. To date, we have not entered into any strategic collaboration with third parties capable of providing these services. In addition, we have not yet marketed or sold any of our drug candidates or entered into successful collaborations for these services in order to ultimately commercialize our drug candidates. If we determine to enter into R & D collaborations during the early phases of drug development, our success will in part depend on the performance of our research collaborators. We will not directly control the amount or timing of resources devoted by our research collaborators to activities related to our drug candidates. Our research

collaborators may not commit sufficient resources to our programs. If any research collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to such collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development- stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements. Manufacturers producing our drug candidates must follow current GMP regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to the current GMP regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process and may delay our ability to receive FDA or foreign regulatory approval of our drug candidates and cause us to fall behind on our business objectives. Establishing strategic collaborations is difficult and time- consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our drug candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, our drug revenues are likely to be lower than if we directly marketed and sold any drugs that we may develop. Management of our relationships with our collaborators will require: ● significant time and effort from our management team; ● coordination of our marketing and R & D programs with the marketing and R & D priorities of our collaborators; and ● effective allocation of our resources to multiple projects. ~~We~~ **Page 72 of 106We** employ the use of certain chemical and biological agents and compounds that may be deemed hazardous and we are therefore subject to various environmental laws and regulations. Compliance with these laws and regulations may result in significant costs, which could materially reduce our ability to become profitable. We use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we safely store these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal. We contract with a third party to properly dispose of these materials and wastes. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may incur significant costs complying with environmental laws and regulations adopted in the future. **We** ~~Page 65 of 95We~~ cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. If we use biological and hazardous materials in a manner that causes injury, we may be liable for damages. Our R & D and manufacturing activities will involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We carry $ 7, 000, 000 casualty and general liability insurance policies. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources and insurance coverage, and our clinical trials or regulatory approvals could be suspended. We depend upon our senior management and their loss or unavailability could put us at a competitive disadvantage. We currently depend upon the efforts and abilities of our management team. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations. We have not obtained, do not own, nor are we the beneficiary of key- person life insurance for all of our key personnel. The Company believes that Dr. Anil Diwan, our President and Executive Chairman is critical to the success of the Company. The Company is a limited beneficiary of a certain amount of key man insurance for Anil Diwan that the Company maintains. However, there can be no assurances that the amount of the key man insurance coverage would be sufficient to provide replacement of this key officer for continuing the Company' s operations in a timely manner, should such an event arise. The Company also maintains a limited amount of Directors and Officers Liability insurance coverage to protect all of its directors and executive officers taken together. There can be no assurance that this D & O coverage will be sufficient to cover the costs of the events that may lead to its invocation, in which case, there could be a substantial impact on the Company' s ability to continue operations, should such an unforeseen event occur. There are conflicts of interest among our officers, directors and stockholders. Certain of our executive officers and directors and their affiliates are engaged in other activities and have interests in other entities on their own behalf or on behalf of other persons. Neither we, nor our stockholders will have any rights in these ventures or their income or profits. Specifically, Dr. Anil Diwan owns approximately 90 % of the capital stock of TheraCour, which as of June 30, ~~2023~~ **2024** , owned ~~4~~ **3** . ~~0~~ **6** % of our common stock, and ~~350~~ **681** , ~~000~~ **859** shares of the Company' s Series A preferred stock, and provides the nanomaterials to the Company with which it intends to develop its products and is the holder of the intellectual property rights the Company uses to conduct its operations. While the Company is not aware of any conflict that has arisen to date, Dr. Diwan may have conflicting fiduciary duties between the Company and TheraCour, for which he must recuse himself from certain decision- making processes of the Company. ~~The~~ **Page 73 of 106The** Company does not allow a conflicted shareholder, director, or executive officer to vote on matters wherein a conflict may be perceived. The conflicted person or entity is not allowed to nominate an alternate person to vote for them either. Other than this safeguard, the Company currently does not have any policy in place, should such a conflict arise. In particular: ● Our executive officers or directors or their affiliates may have an economic interest in, or other business relationship with, partner companies that invest in us. ● Our executive officers or directors or their affiliates

have interests in entities that provide products or services to us. **In** ~~Page 66 of 95In~~ any of these cases: ● Our executive officers or directors may have a conflict between our current interests and their personal financial and other interests in another business venture. ● Our executive officers or directors may have conflicting fiduciary duties to us and the other entity. ● The terms of transactions with the other entity may not be subject to arm' s length negotiations and therefore may be on terms less favorable to us than those that could be procured through arm' s length negotiations. We anticipate entering into contracts with various U. S. government agencies. In contracting with government agencies, we will be subject to various federal contract requirements. Future sales to U. S. government agencies will depend, in part, on our ability to meet these requirements, certain of which we may not be able to satisfy. We may enter into contracts with various U. S. government agencies which have special contracting requirements that give the government agency various rights or impose on the other party various obligations that can make the contracts less favorable to the non- government party. Consequently, if a large portion of our revenue is attributable to these contracts, our business may be adversely affected should the governmental parties exercise any of these additional rights or impose any of these additional obligations. U. S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which subjects us to additional risks. These risks include the ability of the U. S. government to unilaterally: ● suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations; ● terminate our existing contracts; ● reduce the scope and value of our existing contracts; ● audit and object to our contract- related costs and fees, including allocated indirect costs; ● control and potentially prohibit the export of our drug candidates; and ● change certain terms and conditions in our contracts. The U. S. government may terminate any of its contracts with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit on the work completed prior to termination. Termination for default provisions do not permit these recoveries and make us liable for excess costs incurred by the U. S. government in procuring undelivered items from another source. ~~As~~ **Page 74 of 106As** a U. S. government contractor, we may become subject to periodic audits and reviews. Based on the results of these audits, the U. S. government may adjust our contract- related costs and fees, including allocated indirect costs. As part of any such audit or review, the U. S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, compensation and / or management information systems. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U. S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U. S. government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our R & D costs and some marketing expenses, may not be reimbursable or allowed under our contracts. Further, as a U. S. government contractor, we may become subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities to which purely private sector companies are not. **We** ~~Page 67 of 95We~~ may fail to obtain contracts to supply the U. S. government, and we may be unable to commercialize our drug candidates. The U. S. government has undertaken commitments to help secure improved countermeasures against bio- terrorism. The process of obtaining government contracts is lengthy and uncertain, and we would compete for each contract. Moreover, the award of one government contract would not necessarily secure the award of future contracts covering the same drug. If the U. S. government makes significant future contract awards for the supply of its emergency stockpile to our competitors, our business will be harmed and it is unlikely that we will be able to ultimately commercialize our competitive drug candidate. In addition, the determination of when and whether a drug is ready for large scale purchase and potential use will be made by the government through consultation with a number of government agencies, including the FDA, the NIH, the CDC and the Department of Homeland Security. Congress has approved measures to accelerate the development of bio- defense drugs through NIH funding, the review process by the FDA and the final government procurement contracting authority. While this may help speed the approval of our drug candidates, it may also encourage competitors to develop their own drug candidates. We cannot predict with certainty the size of the market, if any for all of the antiviral drugs that the governments may want to stockpile. Consequently, we cannot predict whether sales, if any, to governments will be sufficient to fund our business plan and commence revenue- generating operations. If the U. S. government fails to continue funding bio- defense drug candidate development efforts or fails to purchase sufficient quantities of any future bio- defense drug candidate, we may be unable to generate sufficient revenues to continue operations. While we have not yet received U. S. government funding, we hope to receive funding from the U. S. government for the development of our bio- defense drug candidates. Changes in government budgets and agendas, however, may result in future funding being decreased and de- prioritized, and government contracts typically contain provisions that permit cancellation in the event that funds are unavailable to the government agency. Furthermore, we cannot be certain of the timing of any future funding, and substantial delays or cancellations of funding could result from protests or challenges from third parties. If the U. S. government fails to continue to adequately fund R & D programs, we may be unable to generate sufficient revenues to continue operations. Similarly, if we develop a drug candidate that is approved by the FDA, but the U. S. government does not place sufficient orders for this drug, our future business may be harmed ~~. Failure to remediate a material weakness in internal accounting controls could result in material misstatements in our financial statements. Our management has identified a material weakness in our internal control over financial reporting and has concluded that, due to such material weakness, our disclosure controls and procedures were not effective as of June 30, 2023. The material weakness in internal control over financial reporting resulted from the lack of timely review of the Company' s 10- K. The material weakness had not been remediated as of June 30, 2023. If not remediated, or if we identify further material weaknesses in our internal controls, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our~~

~~financial statements and a failure to meet our reporting and financial obligations, each of which could have a material adverse effect on our financial condition and the trading price of our common stock. We have implemented a remediation plan to remediate this material weakness~~ . Risks Related to the Biotechnology / Biopharmaceutical IndustryThe biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with enterprises equipped with more substantial resources than us. The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition based primarily on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain government approval for testing, manufacturing and marketing. Our Coronavirus drug candidates would compete with the already approved therapies (either EUA or full approvals) **and are subject to the COVID pandemic dissipating** . Page ~~68~~ **75** of ~~95Our~~ **106Our** RSV drug does not have any direct competition at present but there are two protective antibodies as well as ~~two~~ **three** vaccines for RSV, although there are no approved treatments other than the highly toxic last- resort drug, ribavirin. Our shingles drug candidate would compete with Valtrex ®, an approved drug (valacyclovir), and other acyclovir- related nucleoside analogs, and new drugs in the pipeline. FV- 100, a VZV- specific nucleoside analog was in Phase III clinical trials that were terminated. Development of ASP2151, a helicase / primase inhibitor, was terminated due to adverse events in healthy persons in clinical trials. We are not aware of any further drugs in clinical trials for the treatment of shingles. Painkillers such as lidocaine formulations and oxycodone formulations were in clinical trials for symptomatic relief of PHN. Our HSV- 1 and HSV- 2 skin cream drug candidates would compete with branded and unbranded available skin creams, such as Abreva ™, as well as with branded and unbranded oral drug candidates against herpes, such as those based on acyclovir, valacyclovir, gancyclovir, among others. It is not known until after human clinical trials whether our drug candidates provide patient benefits beyond those of these drugs. Other drugs against herpes that are in the pipeline, if approved prior to our drug approval, would also be competition. Several drugs are in clinical trials for HSV- 1 and / or HSV- 2 treatment. These include brincidofovir, cyclopropavir, valamocyclovir, pritelivir, letermovir, as well as antibodies. Their patient benefit profiles are not known at present. Our anti- influenza drug in development, Flucide, would compete with neuraminidase inhibitors Tamiflu and Relenza, anti- influenza drugs that are sold by Roche and Glaxo SmithKline (GSK), respectively. Generic competitors include amantadine and rimantadine, both oral. BioCryst Pharmaceuticals, Inc. has achieved FDA approval for IV Infusions formulations of peramivir, an influenza neuraminidase inhibitor, for the treatment of uncomplicated influenza. Peramivir is approved in Japan and had obtained emergency use authorization in the US. Its effectiveness during multiple clinical trials was found to be severely limited. Recently, a new drug, Xofluza (Baloxavir marboxil), developed by Shionogi, Inc., **and licensed by Roche,** has been approved in Japan, USA, and most of the world ~~by Genetech / Roche~~ . It is an influenza viral endonuclease PA inhibitor. Other drugs in this class are in clinical trials. So are drugs targeting the m7G cap- snatching activity (PB2) of influenza virus such as VX787, and antibodies. Several H5N1 bird flu, and influenza novel H1N1 / 2009 vaccines are also in development worldwide. Several companies are developing anti- influenza drugs and vaccines. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations, many of which have greater market presence and resources than we do. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions, government agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us. We are aware of numerous products under development or manufactured by competitors that are used for the prevention or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that potentially directly compete with our drug candidates even though their approach to such treatment is different. We hope that our drug candidates under development and in clinical trials will address major markets within the anti- viral sector. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of the market introduction of some of our potential drugs or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop drugs, complete pre- clinical testing, clinical trials, approval processes and supply commercial quantities to market are important competitive factors. We expect that competition among drugs approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent protection. Page ~~69~~ **76** of ~~95The~~ **106The** successful development of biopharmaceuticals is highly uncertain. A variety of factors including, pre- clinical study results or regulatory approvals, could cause us to abandon development of our drug candidates. Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in the early phases of development may fail to reach the market for several reasons including: ● pre- clinical study results that may show the product to be less effective than desired (e. g., the study failed to meet its primary objectives) or to have harmful or problematic side effects; ● failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or a IND and later NDA, preparation, discussions with the FDA, an FDA request for additional pre- clinical or clinical data or unexpected safety or manufacturing issues; ● manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economical; and ● the proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized. Success in pre- clinical and early clinical studies does not ensure that large- scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent

regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product to the next, and may be difficult to predict. Risks Related to the Securities Markets and Investments in Our Common StockGeneral securities market uncertainties resulting from international turmoil. International securities markets have become highly unstable in the aftermath of extensive spending by the governments to combat COVID- 19, the rise in energy prices resulting from the Russian war in Ukraine, the political, social and economic effects of this war, changes in governments leading to changes in monetary and fiscal policies, inflation, and other external factors. As a result, the markets may not be available to us for purposes of raising required capital at the time we need it. Should we not be able to obtain financing when required, in the amounts necessary to execute on our plans in full, or on terms which are economically feasible we may be unable to sustain the level of spending required to pursue our strategic plan and may have to reduce the planned future growth and scope of our operations. If we do not meet the continued listing standards of the NYSE American our common stock could be delisted from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions. Our common stock is listed on the NYSE ~~MKT (now known as " NYSE~~ American ~~")~~, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If, however, we fail to satisfy the continued listing standards, such as, for example, the requirement that our shares not trade " for a substantial period of time at a low price per share, " fail to meet stockholders equity requirements, or that we not dispose of our principal operating assets or discontinue a substantial portion of our operations, among other requirements, the NYSE American may issue a non- compliance letter or initiate delisting proceedings. If our securities are delisted from trading on the NYSE American and we are not able to list our securities on another exchange or to have them quoted on NASDAQ, our securities could be quoted on the OTC Bulletin Board or on the " pink sheets. " As a result, we could face significant adverse consequences including: ● a limited availability of market quotations for our securities; ● a determination that our common stock is a " penny stock " which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; Page ~~70~~ **77** of ~~95~~ **106** ● a limited amount of news and analyst coverage for us; and ● a decreased ability to issue additional securities (including pursuant to short- form registration statements on Form S- 3 or obtain additional financing in the future). Our Company is subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended (the " Exchange Act "), which will require us to incur audit fees and legal fees in connection with the preparation of such reports. These additional costs will reduce or might eliminate our **ability to reach** profitability. Our Company is required to file periodic reports with the Commission pursuant to the Exchange Act and the rules and regulations promulgated thereunder. To comply with these requirements, our independent registered auditors will have to review our quarterly financial statements and audit our annual financial statements. Moreover, our legal counsel will have to review and assist in the preparation of such reports. The costs charged by these professionals for such services cannot be accurately predicted at this time, because factors such as the number and type of transactions that we engage in and the complexity of our reports cannot be determined at this time and will have a major effect on the amount of time to be spent by our auditors and attorneys. However, the incurrence of such costs will obviously be an expense to our operations and thus have a negative effect on our ability to meet our overhead requirements and earn a profit. We may be exposed to potential risks under Section 404 of the Sarbanes- Oxley Act of 2002. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, the trading price of our common stock, if a market ever develops, could drop significantly, or we could become subject to Commission enforcement proceedings. Our Common Stock may be considered a " penny stock " and may be difficult to sell. The Commission has adopted regulations which generally define " penny stock " to be an equity security that has a market price of less than $ 5. 00 per share or an exercise price of less than $ 5. 00 per share, subject to specific exemptions. Historically, the price of our common stock has fluctuated greatly. If, the market price of the common stock is less than $ 5. 00 per share and the common stock does not fall within any exemption, it therefore may be designated as a " penny stock " according to Commission rules. The " penny stock " rules impose additional sales practice requirements on broker- dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of $ 1, 000, 000 or annual income exceeding $ 200, 000 or $ 300, 000 together with their spouse). For transactions covered by these rules, the broker- dealer must make a special suitability determination for the purchase of securities and have received the purchaser' s written consent to the transaction before the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the broker- dealer must deliver, before the transaction, a disclosure schedule prescribed by the Commission relating to the penny stock market. The broker- dealer also must disclose the commissions payable to both the broker- dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker- dealers may restrict the ability or decrease the willingness of broker- dealers to sell our common shares, and may result in decreased liquidity for our common shares and increased transaction costs for sales and purchases of our common shares as compared to other securities. Our stock price may be volatile and your investment in our common stock could suffer a decline in value. The price of our Common Stock, as quoted on the NYSE American, may fluctuate significantly in response to a number of factors, many of which are beyond our control. These factors include but are not limited to: ● progress of our products through the regulatory process ● results of preclinical studies and clinical trials; ● announcements of technological innovations or new products by us or our competitors; ● government regulatory action affecting our products or our competitors' products in both the United States and foreign countries; ● developments or disputes concerning patent or proprietary rights; Page ~~71~~ **78** of ~~95~~ **106** ● general market conditions for emerging growth and pharmaceutical companies; ● economic conditions in the United States or abroad; ● actual or anticipated fluctuations in our operating results; ● broad market fluctuations; and ● changes in financial estimates by securities analysts. There is a risk of market fraud. Shareholders should be aware that, according to SEC Release No. 34- 29093, the market for

penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include (1) control of the market for the security by one or a few broker- dealers that are often related to the promoter or issuer; (2) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (3) boiler room practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (4) excessive and undisclosed bid- ask differential and markups by selling broker- dealers; and (5) the wholesale dumping of the same securities by promoters and broker- dealers after prices have been manipulated to a desired level, along with the resulting inevitable collapse of those prices and with consequent investor losses. We are aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker- dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our securities. The occurrence of these patterns or practices could increase the volatility of our share price. A registration of a significant amount of our outstanding restricted stock may have a negative effect on the trading price of our stock. At June 30, ~~2023~~ **2024** , shareholders of the Company held 1, ~~492~~ **330** , ~~542~~ **156** shares of restricted common stock, or approximately ~~12~~ **10** . ~~8~~ **1** % of the outstanding Common Stock. If we were to file a registration statement including all of these shares, and the registration is allowed by the SEC, these shares would be freely tradable upon the effectiveness of the planned registration statement. If investors holding a significant number of freely tradable shares decide to sell them in a short period of time following the effectiveness of a registration statement, such sales could contribute to significant downward pressure on the price of our stock. We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on your investment in our capital stock must come from increases in the fair market value and trading price of the capital stock. We have not paid any cash dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements, which we may enter into with institutional lenders, may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements and any other factors that the board of directors decides is relevant. Therefore, any return on your investment in our capital stock must come from increases in the fair market value and trading price of the capital stock. We may issue additional equity shares to fund the Company' s operational requirements, which would dilute share ownership. The Company' s continued viability depends on its ability to raise capital. Changes in economic, regulatory or competitive conditions may lead to cost increases. Management may also determine that it is in the best interest of the Company to develop new services or products. In any such case additional financing is required for the Company to meet its operational requirements. The sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock and our stock price may decline substantially. ~~The Company is authorized to issue up to 150, 000, 000 shares of common stock without additional approval by shareholders. As of June 30, 2023, we had 11, 698, 497 shares of common stock outstanding, 8, 004 warrants convertible to 8, 004 shares of common stock, and 547, 674 shares of Series A preferred stock convertible into 1, 916, 859 shares of common stock only in the event of a change in control.~~