Risk Factors Comparison 2024-03-18 to 2023-03-17 Form: 10-K

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

Risks Related to our Financial Position and Capital Needs We have suffered recent losses and our future profitability is uncertain. We have incurred net losses of approximately $ **20. 1 million and $** 15. 5 ~~million and $ 14. 3~~ million for the years ended December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** , respectively. Our recent losses have predominantly resulted from research and development expenses for our Trappsol ® Cyclo ™ product and other general operating expenses, including personnel costs. We believe our expenses will continue to increase as we conduct clinical trials and continue to seek regulatory approval for the use of Trappsol ® Cyclo ™ in the treatment of NPC and Alzheimer' s disease. As a result, we expect our operating losses to continue until such time, if ever, that product sales, licensing fees, royalties and other sources generate sufficient revenue to fund our operations. We cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved. Even with the proceeds from our recent securities offerings, we will need additional capital to fund our operations as planned. For the year ended December 31, ~~2022~~ **2023** , our operations used approximately $ ~~15~~ **16** . ~~1~~ **2** million in cash. At December 31, ~~2022~~ **2023** , the Company had a cash balance of approximately $ ~~1~~ **9. 2 million and current liabilities of approximately $ 8** . 5 million ~~and current liabilities of approximately $ 3~~ . **We** ~~5 million. Although we raised approximately $ 3. 7 million in the registered direct offering and concurrent private placement we completed in January 2023, we~~ will need additional capital to maintain our operations, continue our research and development programs, conduct clinical trials, seek regulatory approvals and manufacture and market our products. We will seek such additional funds through public or private equity or debt financings and other sources. We cannot be certain that adequate additional funding will be available to us on acceptable terms, if at all. If we cannot raise the additional funds required for our anticipated operations, we may be required to reduce the scope of or eliminate our research and development programs, delay our clinical trials and the ability to seek regulatory approvals, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency. If we raise additional funds through future offerings of shares of our Common Stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our Common Stock. The report of our independent registered public accounting firm expresses substantial doubt about our ability to continue as a going concern. Our auditors, WithumSmith Brown, PC., have indicated in their report on our consolidated financial statements for the fiscal year ended December 31, ~~2022~~ **2023** , that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses from operations and significant accumulated deficit. In addition, we continue to experience negative cash flows from operations. A " going concern " opinion could impair our ability to finance our operations through the sale of equity. Our ability to continue as a going concern will depend upon the availability of equity financing which represents the primary source of cash flows that will permit us to meet our financial obligations as they come due and continue our research and development efforts. We have not received approval for any drug candidate for commercial sale and, as a result, we have never generated any revenue from the sale of biopharmaceutical products, and expect to continue to incur significant financial losses in the future, which makes it difficult to assess our future viability. While we sell cyclodextrins for use and research in numerous industries, we have not yet received the necessary regulatory approvals to commercially sell any biopharmaceutical products. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk, including risks related to the regulatory approval process. Because the focus of our business has transitioned to the development of cyclodextrin- based products for the treatment of disease, we anticipate that our expenses will increase substantially as we: ● continue our ongoing and planned development of Trappsol ® Cyclo ™ for multiple indications; ● initiate, conduct and complete ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates; ● seek marketing approvals for product candidates that successfully complete clinical trials; and ● establish a sales, marketing **,** and distribution infrastructure to commercialize products for which we may obtain marketing approval. We will continue to incur significant losses until such time, if ever, as we are able to commercialize our drug candidates. If we are not able to do so we may not sustain a viable business. Risks Related to Product Development, Regulatory Approval and Commercialization We are largely dependent upon the success of our Trappsol ® Cyclo ™ product, which may never receive regulatory approval. Our lead drug candidate, Trappsol ® Cyclo ™ is the focus of much of our management team' s development efforts. The product is currently designated as an orphan drug for the treatment of NPC in the United States and Europe. We plan to continue to make substantial investment in continued research and development of our Trappsol ® Cyclo ™ product in connection with obtaining approval for marketing the product for the treatment of NPC, as well as Alzheimer' s disease. The potential population of NPC patients is small, and our ability to market the drug for use other than research is severely constrained by regulatory restrictions. In the course of its development, our Trappsol ® Cyclo ™ drug product will be subject to extensive and rigorous government regulation through the European Medicines Agency in the E. U. and through the Food and Drug Administration (FDA) in the United States. Regulatory approval in any jurisdiction cannot be guaranteed. There can be no guarantees that our product will be effective and safe in the treatment of NPC, Alzheimer' s disease or any other disease nor is there any guarantee that it will be deemed by the regulatory agencies of any jurisdiction to be effective and safe. Despite the time and expense involved in developing a drug candidate, failure of a drug candidate can occur at any stage of development and for many reasons, including without limitation negative or inconclusive results from pre- clinical data or clinical trials. Failure to comply with applicable regulatory requirements in any jurisdiction, either before or after product approval, may subject us to administrative or judicially imposed sanctions. Even if Trappsol ® Cyclo ™ receives regulatory

approval, we may not be successful in our commercialization efforts and Trappsol ® Cyclo ™ may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success. Even if Trappsol ® Cyclo ™ receives regulatory approval, we may not be successful in our commercialization efforts and market acceptance by physicians, patients, third- party payors and others in the medical community may be less than estimated. Market acceptance will require us to build and maintain strong relationships with healthcare professionals involved in the treatment of NPC. The number of healthcare professionals associated with treatment centers that address NPC is limited. A failure to build or maintain these important relationships with these healthcare professionals and treatment centers could result in lower market acceptance. Our efforts to educate physicians, patients, third- party payors and others in the medical community on the benefits of Trappsol ® Cyclo ™ may require significant resources and may never be successful. The degree of market acceptance of Trappsol ® Cyclo ™, if approved for commercial sale, will depend on a number of factors, including: ● its efficacy; ● limitations or warnings or any restrictions on the use of Trappsol ® Cyclo ™, together with other medications, and the prevalence and severity of any side effects; ● the availability and efficacy of alternative treatments; ● the effectiveness of sales and marketing efforts and the strength of marketing and distribution support; ● the cost- effectiveness of Trappsol ® Cyclo ™ compared to alternative therapies and the ability to offer such drug for sale at competitive prices; and ● availability and amount of coverage and reimbursement from government payors, managed care plans and other third- party payors. The results of our clinical trials may not support our product claims or may result in the discovery of adverse side effects. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that any regulatory authority whose approval we will require in order to market and sell our products in any territory will agree with our conclusions regarding them. Success in pre- clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that clinical trials will replicate the results of prior trials and pre- clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate' s profile. Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including FDA approval. Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from completed or ongoing clinical trials. We estimate that clinical trials of Trappsol ® Cyclo ™ for the treatment of NPC will continue for several years, but they may take significantly longer to complete. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates, including but not limited to: ● delays in securing clinical investigators or trial sites for the clinical trials; ● delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial; ● slower than anticipated patient recruitment and enrollment; ● negative or inconclusive results from clinical trials; ● unforeseen safety issues; ● uncertain dosing issues; ● an inability to monitor patients adequately during or after treatment; and ● problems with investigator or patient compliance with the trial protocols. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier clinical trials for Trappsol ® Cyclo ™, we do not know whether any Phase III or other clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market Trappsol ® Cyclo ™. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for Trappsol ® Cyclo ™ may be adversely impacted. Later discovery of previously unknown problems could limit our ability to market or sell Trappsol ® Cyclo ™, even if it is initially approved, and can expose us to product liability claims. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with any third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: ● refusals or delays in the approval of applications or supplements to approved applications; ● refusal of a regulatory authority to review pending market approval applications or supplements to approved applications; ● restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures; ● fines, warning letters, or holds on clinical trials; ● import or export restrictions; ● injunctions or the imposition of civil or criminal penalties; ● restrictions on product administration, requirements for additional clinical trials, or changes to product labeling requirements; or ● recommendations by regulatory authorities against entering into governmental contracts with us. Discovery of previously unknown problems or risks relating to our product could also subject us to potential liabilities through product liability claims. If we do not obtain required approvals in other countries in which we aim to market our products, we will be limited in our ability to export or sell the products in those markets. Our lack of experience in conducting clinical trials in any jurisdiction may negatively impact the approval process in those jurisdictions where we intend to seek approval of Trappsol ® Cyclo ™. If we are unable to obtain and maintain required approval from one or more foreign jurisdictions where we would like to sell Trappsol ® Cyclo ™, we will be unable to market products as intended, our international market opportunity will be limited and our results of operations will be harmed. We rely in part on third parties for research and clinical trials for products using Trappsol ® Cyclo ™. We rely on contract research organizations (" CROs "), academic institutions, corporate partners, and other third parties to assist us in managing, monitoring, and otherwise carrying out clinical trials and research activities. We rely or will rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted

them entirely on our own. Although we rely on these third parties to manage the data from clinical trials, we will be responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Our failure, or the failure of third parties on which we rely, to comply with the strict requirements relating to conducting, recording, and reporting the results of clinical trials, or to follow good clinical practices, may delay the regulatory approval process or cause us to fail to obtain regulatory approval for Trappsol ® Cyclo ™. We currently have no marketing and sales organization for our pharmaceutical candidates and may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue. We have no internal sales, marketing or distribution capabilities for the sale of biopharmaceutical products. If any of our drug candidates ultimately receives regulatory approval, we may not be able to effectively market and distribute it. We may have to seek collaborators, especially for marketing and sales outside of the United States, or invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including: ● we may not be able to attract and build an effective marketing department or sales force; ● the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenue generated by our product candidates that we may develop, in- license or acquire; and ● our direct sales and marketing efforts may not be successful. We rely upon third parties for the manufacture of Trappsol ® Cyclo ™ and are dependent on their quality and effectiveness. Trappsol ® Cyclo ™ requires precise, high- quality manufacturing. The failure to achieve and maintain high manufacturing standards, including the failure to conform to c- GMP (current Good Manufacturing Practice), or to detect or control anticipated or unanticipated manufacturing errors or the frequent occurrence of such errors, could result in discontinuance or delay of ongoing or planned clinical trials, delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals, patient injury or death, and other problems that could seriously hurt our business. Contract drug manufacturers often encounter difficulties involving production yields, quality control and quality assurance and shortages of qualified personnel. These manufacturers are subject to stringent regulatory requirements, including the FDA' s c- GMP regulations and similar foreign laws and standards. If our contract manufacturers fail to maintain ongoing compliance at any time, the production of our product candidates could be interrupted, resulting in delays or discontinuance of our clinical trials, additional costs and loss of potential revenues. We face competition from well- funded companies to treat NPC. We face competition from other entities, including pharmaceutical and biotechnology companies and governmental institutions that are working on supporting orphan drug designations and clinical trials for the neurological manifestations of NPC. Some of these entities are well- funded, with more financial, technical and personnel resources than we have, and have more experience than we do in designing and implementing clinical trials. If we are unable to compete effectively against our current or future competitors, sales of our Trappsol ® Cyclo ™ product may not grow and our financial condition may suffer. Our business and operations would suffer in the event of computer system failures or security breaches. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations, or CROs, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and / or result in the loss, misappropriation, and / or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, the COVID- 19 pandemic has resulted in a significant number of our employees and partners working remotely, which increases the risk of a data breach or issues with data and cybersecurity. To the extent that any disruption or security breach results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed. Risks Related to Our Intellectual Property The rights we rely upon to protect our unpatented trade secrets may be inadequate. To manufacture and produce Trappsol ® Cyclo ™, we rely primarily on unpatented trade secrets, know- how and technology which are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. We seek to protect trade secrets, in part, by entering into confidentiality agreements with third- party manufacturers, employees, consultants and others. These parties may breach or terminate these agreements or may refuse to enter into such agreements with us, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other proprietary information and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, we or others may unintentionally or willfully disclose our proprietary information to competitors. If we fail to

maintain trade secret protection, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know- how, we would not be able to assert our trade secrets against them and our business could be harmed. We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and / or unenforceable. We have **received notices of allowances from the USPTO and the European Patent Officer regarding our patent applications for methods of treating Alzheimer' s disease. We have** patent applications pending with respect to the treatment of Alzheimer' s disease with Trappsol ® Cyclo ™. However, we cannot predict: ● if and when patents may issue based on our patent applications; ● the scope of protection of any patent issuing based on our patent applications; ● whether the claims of any patent issuing based on our patent applications will provide protection against competitors; ● whether or not third parties will find ways to invalidate or circumvent our patent rights, or claim co- ownership rights in our patent rights, which may impact our ability to enforce our patent rights against third parties; ● whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or ● whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose. We cannot be certain that the claims in our pending patent applications will be considered patentable by the U. S. Patent and Trademark Office or by patent offices in foreign countries. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us and threaten our ability to commercialize our product candidates. It is possible that third parties with whom we have collaborated may contend that they co- own patent rights we have filed, which, if correct and in the absence of an agreement to the contrary, could prevent us from asserting the patent rights against our competitors. Furthermore, in the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. We are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our product candidates. There is a substantial amount of litigation over patent and other intellectual property rights in the biotechnology industry. Whether or not a product infringes a patent involves complex legal and factual considerations, the determination of which is often uncertain. Searches typically performed to identify potentially infringed patents of third parties are often not conclusive and, because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our current or future products may infringe or be alleged to infringe. In addition, our competitors or other parties may assert that our product candidates and the methods employed may be covered by patents held by them. If any of our products infringes a valid patent, we could be prevented from manufacturing or selling such product unless we are able to obtain a license or able to redesign the product in such a manner as to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid infringement, nor does a later redesign protect the Company from prior infringement. We are aware of third party U. S. patents and patent applications, which may be relevant to our lead product candidate Trappsol ® Cyclo ™ for treating Niemann- Pick Type C disease. Although we believe that we would not infringe a valid claim of those patents or pending patent applications, if issued, the owner of the patent rights may disagree with our assessment and bring an infringement action against us. There is no assurance that a court would find in our favor on questions of infringement or validity. Infringement and other intellectual property claims, with or without merit, can be expensive and time- consuming to litigate and can divert our management' s attention from operating our business. We may need to initiate lawsuits to protect or enforce our intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market. In order to protect or enforce our intellectual property rights, we may initiate patent, trademark and related litigation against third parties, such as infringement suits or requests for injunctive relief. Our ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who we believe to be infringing its rights. Any lawsuits that we initiate could be expensive, take significant time and divert our management' s attention from other business concerns and the outcome of litigation to enforce our intellectual property rights in patents, trade secrets or trademarks is highly unpredictable. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, or adversely affect our ability to distribute any products that are subject to such litigation. In addition, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, including attorney fees, if any, may not be commercially valuable. Risks Related to Legal and Regulatory Compliance Matters The pharmaceutical business is subject to increasing government regulation and reform, including with respect to price controls, reimbursement and access to drugs, which could adversely affect our future revenues and profitability. To the extent our products are developed, commercialized, and successfully introduced to market, they may not be considered cost- effective, and third- party or government reimbursement might not be available or sufficient. Globally, governmental and other third- party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U. S. to continue. If we obtain the required regulatory approval to sell our drug candidates, we will be subject to substantial pricing, reimbursement, and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and the implementation of U. S. health care reform legislation that is increasing these pricing pressures. The Patient Protection

and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, instituted comprehensive health care reform, and includes provisions that, among other things, reduce and / or limit Medicare reimbursement, and impose new and / or increased taxes. The future of the Affordable Care Act and its constituent parts are uncertain at this time. In almost all markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe and in other countries is and will be determined by national regulatory authorities. Reimbursement decisions from one or more of the European markets may impact reimbursement decisions in other European markets. A variety of factors are considered in making reimbursement decisions, including whether there is sufficient evidence to show that treatment with the product is more effective than current treatments, that the product represents good value for money for the health service it provides, and that treatment with the product works at least as well as currently available treatments. The continuing efforts of government and insurance companies, health maintenance organizations, and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers, and collaborative partners, as well as the availability of capital. United States federal and state privacy laws, and equivalent laws of other nations, may increase our costs of operation and expose us to civil and criminal sanctions. Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products, affect our or our collaborators' ability to offer our products in certain locations, or cause regulators to reject, limit or disrupt our clinical trial activities. We and our collaborators may be subject to federal, state and foreign data protection laws and regulations (i. e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state personal information laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we knowingly use or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. Risks Related to Employee Matters We are dependent on our executive officers, and we may not be able to pursue our current business strategy effectively if we lose them. Our success to date has largely depended on the efforts and abilities of our executive officers, namely N. Scott Fine, our Chief Executive Officer, Jeffrey L. Tate, Ph. D., our Chief Operating Officer, and **Josh Fine** ~~Lise Kjems, MD, PhD~~ , our Chief ~~Medical~~ **Financial** Officer. Our ability to manage our operations and meet our business objectives could be adversely affected if, for any reason, such officers do not remain with us. Our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards. We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) U. S. laws and regulations or those of foreign jurisdictions, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If we fail to comply with the U. S. federal Anti- Kickback Statute and similar state and foreign country laws, we could be subject to criminal and civil penalties and exclusion from federally funded healthcare programs including the Medicare and Medicaid programs and equivalent third country programs, which would have a material adverse effect on our business and results of operations. A provision of the Social Security Act, commonly referred to as the federal Anti- Kickback Statute, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, directly or indirectly, in cash or in kind, to induce or reward the referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or

services payable, in whole or in part, by Medicare, Medicaid or any other federal healthcare program. The federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, many states have adopted laws similar to the federal Anti- Kickback Statute that apply to activity in those states, and some of these laws are even broader than the federal Anti- Kickback Statute in that their prohibitions may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the source of payment. Violations of the federal Anti- Kickback Statute may result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs. While we believe our operations will be in compliance with the federal Anti- Kickback Statute and similar state laws, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time- consuming and costly to us and could divert management' s attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the federal Anti- Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition. Risks Related To Our Fine Chemical Business A small number of our customers account for a substantial portion of our revenue, and the loss of any of these customers would materially decrease our revenues. In ~~2022~~ **2023** , ~~three~~ **two** major customers accounted for ~~68~~ **72** % of total revenues. Accounts receivable balances for these major customers represents ~~19~~ **77** % of total accounts receivable at December 31, ~~2022~~ **2023** . We have a supply contract with only one of our major customers. The loss of one of these customers would materially decrease our revenues if we were unable to replace such customers. We are dependent on certain third- party suppliers. We purchase the Trappsol ® cyclodextrin products we sell from third- party suppliers and depend on those suppliers for the cyclodextrins we use in our Aquaplex ® products. We are also dependent on outside manufacturers that use lyophilization techniques for our Aquaplex ® products. We purchase substantially all of our Trappsol ® products from bulk manufacturers and distributors in the U. S., Japan, China, and Europe. Although products are available from multiple sources, an unexpected interruption of supply, or material increases in the price of products, for any reason, such as regulatory requirements, import restrictions, loss of certifications, power interruptions, fires, hurricanes, war or other events could have a material adverse effect on our business, results of operations, financial condition and cash flows. We may be negatively affected by currency exchange rate fluctuations. Our earnings and cash flows are influenced by currency fluctuations due to the geographic diversity of our suppliers, which may have a significant impact on our financial results. As we buy inventory from foreign suppliers, the change in the value of the U. S. dollar in relation to the Euro, Yen and Yuan has an effect on our cost of inventory, and will continue to do so. We buy most of our products from outside the U. S. using U. S. dollars. Our main supplier of specialty cyclodextrins and complexes, Cyclodextrin Research & Development Laboratory, is located in Hungary and its prices are set in Euros. The cost of our bulk inventory often changes due to fluctuations in the U. S. dollar. These products currently represent a significant portion of our revenues. When we experience short- term increases in currency fluctuation or supplier price increases, we are often not able to raise our prices sufficiently to maintain our historical margins and therefore, our margins on these sales may decline. If the U. S. dollar weakens against foreign currencies, the translation of these foreign currency denominated transactions may adversely affect our results of operations and financial condition. Risks Related To Our Common Stock The market price of our Common Stock may be highly volatile, and you could lose all or part of your investment. The trading price of our Common Stock and warrants is likely to be volatile. This volatility may prevent you from being able to sell your securities at or above the price you paid for your securities. Our stock price and warrant price could be subject to wide fluctuations in response to a variety of factors, which include: ● whether we achieve our anticipated corporate objectives; ● changes in financial or operational estimates or projections; ● termination of the lock- up agreement or other restrictions on the ability of our stockholders and other security holders to sell shares after this offering; and ● general economic or political conditions in the United States or elsewhere. In addition, the stock market in general, and the stock of clinical stage biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Common Stock, regardless of our actual operating performance. If we are delisted from The Nasdaq Capital Market, and our shares become subject to the penny stock rules, it would become more difficult to trade our shares. The SEC has adopted rules that regulate broker- dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $ 5. 00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not maintain a listing on Nasdaq and if the price of our Common Stock is less than $ 5. 00, our Common Stock will be deemed a penny stock. The penny stock rules require a broker- dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker- dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser' s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our Common Stock, and therefore stockholders may have difficulty selling their shares. Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our securities **. During fiscal 2023, we receive notices of non- compliance with the regulatory requirements for Nasdaq** . If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to de- list our securities. Such a de- listing would likely have a negative effect on the price of our Common Stock and would impair your ability to sell or purchase our Common Stock when you wish to do so. In the event of a de- listing, we would take actions to restore our compliance with Nasdaq' s listing

requirements, but we can provide no assurance that any such action taken by us would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our Common Stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with Nasdaq' s listing requirements. We will indemnify and hold harmless our officers and directors to the maximum extent permitted by Nevada law. Our bylaws provide that we will indemnify and hold harmless our officers and directors against claims arising from our activities to the maximum extent permitted by Nevada law. If we were called upon to perform under our indemnification agreement, then the portion of our assets expended for such purpose would reduce the amount otherwise available for our business. Because we do not expect to pay dividends for the foreseeable future, investors seeking cash dividends should not purchase shares of Common Stock. We have never declared or paid any cash dividends on our Common Stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including but not limited to our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. Accordingly, investors seeking cash dividends should not purchase our shares. ~~30~~