Risk Factors Comparison 2024-06-17 to 2023-06-21 Form: 10-K

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

Risks Related to Our Business We have a history of losses, we expect to continue to incur losses and we may never achieve profitability and our March 31, ~~2023~~ **2024** audited consolidated financial statements included disclosure that casts substantial doubt regarding our ability to continue as a going concern. We reported a net loss of $ ~~5~~ **4** , ~~151~~ **835** , 000 and $ 5, ~~086~~ **151** , 000 for the years ended March 31, **2024 and** 2023 ~~and 2022~~ , respectively. At March 31, **2024 and** 2023 ~~and 2022~~ , our accumulated deficit amounted to $ **194, 349, 000 and $** 189, 514 ~~, 000 and $ 184, 363~~ , 000, respectively. We had working capital of $ ~~10~~ **8** , ~~081~~ **829** , 000 and $ 10, ~~611~~ **081** , 000 as of March 31, **2024 and** 2023 ~~and 2022~~ , respectively. During the years ended March 31, **2024 and** 2023 ~~and 2022~~ , net cash used in operating activities amounted to $ **2, 398, 000 and $** 6, 152 ~~, 000 and $ 4, 248~~ , 000, respectively. As of March 31, ~~2023~~ **2024** , we had cash and cash equivalents of $ 3, ~~820~~ **128** , 000. We spent the most recent years working to reduce our losses and have made significant progress. However, we expect to continue incurring losses for the foreseeable future. We may never achieve or sustain profitability. We must raise additional capital to pursue our product development initiatives, penetrate markets for the sale of our products and continue as a going concern. We cannot provide any assurance that we will raise additional capital. We believe that we have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations, or other means. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our efforts to further commercialize our products, which are critical to the realization of our business plan and to our future operations. These matters raise substantial doubt about our ability to continue as a going concern or become profitable. We depend on third party distributors and intend to continue to license or collaborate with third parties in various potential markets, and events involving these strategic partners or any future collaboration could delay or prevent us from developing or commercializing products. Our business strategy and our short- and long- term operating results depend in part on our ability to execute on existing strategic collaborations and to license or partner with new strategic partners. We believe collaborations allow us to leverage our resources and technologies and to access markets that are compatible with our own core areas of expertise while avoiding the cost of establishing or maintaining a direct sales force in each market. We may incur significant costs in the use of third parties to identify and assist in establishing relationships with potential collaborators. We currently use distributors for most of our products. We have limited control over the amount and timing of resources that our current partners or any future collaborators devote to our collaborations or potential products. These partners may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our partners may not develop or commercialize products that arise out of our collaborative arrangements or devote sufficient resources to the development, manufacture, marketing or sale of these products. To penetrate our target markets, we may need to enter into additional collaborative agreements to assist in the development and commercialization of products. Establishing strategic collaborations is difficult and time- consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Our discussions with potential collaborators may not lead to the establishment of new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property filings and next generation formations. By entering into collaboration, we may preclude opportunities to collaborate with other third parties who do not wish to associate with our existing third- party strategic partners. Moreover, in the event of termination of a collaboration agreement, termination negotiations may result in less favorable terms. Mexican tax law prevents us from deducting intercompany interest expense incurred by our Mexico subsidiary Oculus Technologies of Mexico, S. A. de C. V and requires withholding tax on payments remitted to the US. At the same time, we are unable to recognize tax benefits for foreign tax credits for U. S. tax purposes. Since 2004, we loaned substantial amounts to our Mexico subsidiary Oculus Technologies of Mexico, S. A. de C. V. at various interest rates to fund their operations. As of March 31, ~~2023~~ **2024** , our Mexico subsidiary owes approximately $ ~~12~~ **13** . ~~3~~ **4** million in principal, $ ~~11~~ **9** . ~~1~~ **8** million in technical assistance payments and $ ~~21~~ **12** . ~~8~~ **6** million in accrued interest. The intercompany loans mature in 2027. There is no guarantee that our Mexican subsidiary will be able to pay any or all of the amounts due. If we were to forgive the debt or if we were to convert the debt to equity, it would be subject to Mexico income tax at 30 %, or approximately $ 10. ~~2~~ **7** million, as well as Mexican withholding tax of 15 %. Mexico' s thin capitalization rules also require taxpayers to maintain a debt- to- equity ratio of 3: 1. Any interest paid to foreign related parties that results in indebtedness exceeding a ratio of 3: 1 to their stockholder' s equity is not deductible for Mexican corporate income tax purposes and we did not meet that condition. Therefore, we have not been able to deduct the intercompany interest on our Mexico tax returns since 2004. It has prevented our Mexico subsidiary from accruing net operating losses in Mexico to offset potential future profits. At the same time the intercompany interest income in the United States decreases our U. S. net operating losses and reduces our ability to apply these carryforwards to offset future taxable income in the United States. In addition, any interest paid to a foreign lender is subject to Mexico withholding tax of 15 %. We also have interest owed on our intercompany technical assistance agreement and royalty withholding of 10 % on our technical assistance agreement. This would amount to approximately $ 4. ~~2~~ **7** million in Mexico withholding tax at March 31, ~~2023~~ **2024** , if all of the interest and technical assistance were to be repaid to us. In general, the foreign related party parent can then claim a credit for these withholding taxes on their U. S. income tax return. However, because of our substantial U. S. net operating losses, we are prevented from claiming any credit on any withholding tax for U. S. income tax purposes. Any such failure to pay intercompany debt, inability to deduct income

taxes or apply credits, or liability for tax payments could have a material adverse effect on our business, financial condition, and results of operations. We rely on a number of key customers who may not consistently purchase our products in the future and if we lose any one of these customers, our revenues may decline. Although we have a significant number of customers in each of the geographic markets that we operate in, we rely on certain key customers for a significant portion of our revenues. For the year ended March 31, ~~2023~~ **2024** , customer A represented ~~16~~ **17** %, customer B represented ~~18~~ **15** % and customer C represented ~~11~~ **14** % of net revenues. For the year ended March 31, ~~2022~~ **2023** , customer A represented ~~21~~ **11** %, customer B represented ~~17~~ **16** % ~~,~~ and customer C represented ~~10~~ **18** % of net revenues. In the future, a small number of customers may continue to represent a significant portion of our total revenues in any given period. These customers may not consistently purchase our products at a particular rate over any subsequent period. The loss of any of these customers could adversely affect our revenues. A majority of our business is conducted outside of the United States, exposing us to additional risks that may not exist in the United States, which in turn could cause our business and operating results to suffer. We have material international operations in Mexico, Asia and Europe. During the years ended March 31, **2024 and** 2023 ~~and 2022~~ , approximately **76 % and** 74 ~~% and 70~~ % of our total revenue, respectively, were generated from sales outside of the United States. Our business is highly regulated for the use, marketing and manufacturing of our HOCl- based products both domestically and internationally. Our international operations are subject to risks, including: · local political or economic instability; · continuing restrictions related to the Covid- 19 pandemic; · changes in exchange rates; · changes in governmental regulation; · changes in import / export duties; · trade restrictions; · lack of experience in foreign markets; · difficulties and costs of staffing and managing operations in certain foreign countries; · work stoppages or other changes in labor conditions; · difficulties in collecting accounts receivables on a timely basis ~~or~~ , **or** at all; and · adverse tax consequences or overlapping tax structures. We plan to continue to market and sell our products internationally to respond to customer requirements and market opportunities. We currently have manufacturing facilities in Mexico. Establishing operations in any foreign country or region presents risks such as those described above as well as risks specific to the particular country or region. In addition, until a payment history is established over time with customers in a new geographic area or region, the likelihood of collecting receivables generated by such operations could be less than our expectations. As a result, there is a greater risk that the reserves set with respect to the collection of such receivables may be inadequate. If our operations in any foreign country are unsuccessful, we could incur significant losses and we may not achieve profitability. In addition, changes in policies or laws of the United States or foreign governments resulting in, among other things, changes in regulations and the approval process, higher taxation, currency conversion limitations, restrictions on fund transfers or the expropriation of private enterprises, could reduce the anticipated benefits of our international expansion. If we fail to realize the anticipated revenue growth of our future international operations, our business and operating results could suffer. If we fail to obtain, or experience significant delays in obtaining, additional regulatory clearances or approvals to market our current or future products, we may be unable to commercialize these products. The developing, testing, manufacturing, marketing and selling of medical technology products is subject to extensive regulation by numerous governmental authorities in the United States and other countries. The process of obtaining regulatory clearance and approval of medical technology products is costly and time consuming. Even though their underlying product formulations may be the same or similar, our products are subject to different regulations and approval processes depending upon their intended use. The FDA generally clears marketing of a medical device through the 510 (k) pre- market clearance process if it is demonstrated the new product has the same intended use and the same or similar technological characteristics as another legally marketed Class II device, such as a device already cleared by the FDA through the 510 (k) premarket notification process, and otherwise meets the FDA' s requirements. Product modifications, including labeling the product for a new intended use, may require the submission of a new 510 (k) clearance and FDA approval before the modified product can be marketed. **On November 30, 2023, the FDA issued a proposed rule to classify certain wound dressings and liquid wound washes, including hypochlorous acid, into Class II medical devices. If finalized, we would be required to submit new 510 (k) applications for our products and to demonstrate compliance with special controls that require specific information relating to performance testing and technical specifications, specific labeling requirements, and other requirements. While we believe we will be able to demonstrate compliance with these special controls if the proposed rule is finalized, there is no guarantee that the FDA will issue new clearance letters for our products, and the process of obtaining additional clearances may be costly and time consuming.** In addition, we do not know whether the necessary approvals or clearances will be granted or delayed for future products. The FDA could request additional information, changes to product formulation (s) or clinical testing that could adversely affect the time to market and sale of products as drugs. If we do not obtain the requisite regulatory clearances and approvals, we will be unable to commercialize our products and may never recover any of the substantial costs we have invested in the development of HOCl. Distribution of our products outside the United States is subject to extensive government regulation. These regulations, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations, vary from country to country. We do not know whether we will obtain regulatory approvals in such countries or that we will not be required to incur significant costs in obtaining or maintaining these regulatory approvals. In addition, the export by us of certain of our products that have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Failure to obtain necessary regulatory approvals, the restriction, suspension or revocation of existing approvals or any other failure to comply with regulatory requirements would have a material adverse effect on our future business, financial condition, and results of operations . If our products do not gain..... purchased insurance on our accounts receivable balances . If we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market. Regulatory approvals or clearances that we currently have and that we may receive in the future are subject to limitations on the indicated uses for which the products may be marketed, and any future approvals could contain requirements for potentially costly post- marketing follow- up studies. If the FDA determines that our promotional materials or activities

constitute promotion of an unapproved use or we otherwise fail to comply with FDA regulations, we may be subject to regulatory enforcement actions, including warning letters, injunctions, seizures, civil fines or criminal penalties. In addition, the manufacturing, labeling, packaging, adverse event reporting, storing, advertising, promoting, distributing and record- keeping for approved products are subject to extensive regulation. We are subject to continued supervision by European regulatory agencies relating to our CE markings and are required to report any serious adverse incidents to the appropriate authorities. Our manufacturing facilities, processes and specifications are subject to periodic inspection by the FDA, Mexican and other regulatory authorities and, from time to time, we may receive notices of deficiencies from these agencies as a result of such inspections. Our failure to continue to meet regulatory standards or to remedy any deficiencies could result in restrictions being imposed on our products or manufacturing processes, fines, suspension or loss of regulatory approvals or clearances, product recalls, termination of distribution, product seizures or the need to invest substantial resources to comply with various existing and new requirements. In the more egregious cases, criminal sanctions, civil penalties, disgorgement of profits or closure of our manufacturing facilities are possible. The subsequent discovery of previously unknown problems with HOCl, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of our products, and could include voluntary or mandatory recall or withdrawal of products from the market. New government regulations may be enacted and changes in FDA policies and regulations and, their interpretation and enforcement, could prevent or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. Therefore, we do not know whether we will be able to continue to comply with any regulations or that the costs of such compliance will not have a material adverse effect on our future business, financial condition, and results of operations. If we are not able to maintain regulatory compliance, we will not be permitted to market our products and our business would suffer. If any of our third- party contractors fail to perform their responsibilities to comply with FDA rules and regulations,the manufacture,marketing and sales of our products could be delayed,which could decrease our revenues.Supplying the market with our HOCl technology products requires us to manage relationships with an increasing number of collaborative partners,suppliers and third- party contractors.As a result,our success depends partially on the success of these third parties in performing their responsibilities to comply with FDA rules and regulations.Although we pre- qualify our contractors and we believe that they are fully capable of performing their contractual obligations,we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities.For example,we and our suppliers are required to comply with the FDA' s quality system regulations,which cover the methods and documentation of the design,testing,production,control,quality assurance,labeling,packaging,storage and shipping of our products.The FDA enforces the quality system regulation through inspections.If any of our partners or contractors fail to perform their obligations in an adequate and timely manner or fail to comply with the FDA' s rules and regulations,including failure to comply with quality systems regulations or a corrective action submitted to the FDA after notification by the FDA of a deficiency is deemed insufficient,then the manufacture,marketing and sales of our products could be delayed.Our products could be detained or seized,the FDA could order a recall,or require our partner to replace or offer refunds for our products.The FDA could also require our partner,and depending on our agreement with our partner,us,to notify healthcare professionals and others that the products present unreasonable risks of substantial harm to the public health.If any of these events occur,the manufacture,marketing and sales of our products could be delayed which could decrease our revenues.If we fail to comply with the FDA' s rules and regulations and are subject to an FDA recall as part of an FDA enforcement action,the associated costs could have a material adverse effect on our business,financial position,results of operations and cash flows.Our Company,our products,the manufacturing facilities for our products,the distribution of our products,and our promotion and marketing materials are subject to strict and continual review and periodic inspection by the FDA and other regulatory agencies for compliance with pre- approval and post- approval regulatory requirements.If we fail to comply with the FDA' s rules and regulations,we could be subject to an enforcement action by the FDA.The FDA could undertake regulatory actions,including seeking a consent decree,recalling or seizing our products,ordering a total or partial shutdown of production,delaying future marketing clearances or approvals,and withdrawing or suspending certain of our current products from the market.A product recall,restriction,or withdrawal could result in substantial and unexpected expenditures,destruction of product inventory,and lost revenues due to the unavailability of one or more of our products for a period of time,which could reduce profitability and cash flow.In addition,a product recall or withdrawal could divert significant management attention and financial resources.If any of our products are subject to an FDA recall,we could incur significant costs and suffer economic losses.Production of our products could be suspended and we could be required to establish inventory reserves to cover estimated inventory losses for all work- in-process and finished goods related to products we,or our third- party contractors,manufacture.A recall of a material amount of our products could have a significant,unfavorable impact on our future gross margins.If our products fail to comply with FDA and other governmental regulations,or our products are deemed defective,we may be required to recall our products and we could suffer adverse public relations that could adversely impact our sales,operating results,and reputation which would adversely affect our business operations.We may be exposed to product recalls,including voluntary recalls or withdrawals,and adverse public relations if our products are alleged to cause injury or illness,or if we are alleged to have mislabeled or misbranded our products or otherwise violated governmental regulations.Governmental authorities can also require product recalls or impose restrictions for product design,manufacturing,labeling,clearance,or other issues.For the same reasons,we may also voluntarily elect to recall,restrict the use of a product or withdraw products that we consider below our standards,whether for quality,packaging,appearance or otherwise,in order to protect our brand reputation.Product recalls,product liability claims,even if unmerited or unsuccessful,or any other events that cause consumers to no longer associate our brand with high quality and safe products may also result in adverse publicity,hurt the value of our brand,harm our reputation among our customers and other healthcare professionals who use or recommend the products,lead to a decline in consumer confidence in and demand for our products,and lead to increased scrutiny by federal and state regulatory agencies of our operations,any of

which could have a material adverse effect on our brand,business,performance,prospects,value,results of operations and financial condition. We may experience difficulties in manufacturing our products, which could prevent us from commercializing one or more of our products. The machines used to manufacture our products are complex, use complicated software and must be monitored by highly trained engineers. Slight deviations anywhere in our manufacturing process, including quality control, labeling, and packaging, could lead to a failure to meet the specifications required by the FDA, the Environmental Protection Agency, European notified bodies, Mexican regulatory agencies and other foreign regulatory bodies, which may result in lot failures or product recalls. If we are unable to obtain quality internal and external components, mechanical and electrical parts, if our software contains defects or is corrupted, or if we are unable to attract and retain qualified technicians to manufacture our products, our manufacturing output of HOCl, or any other product candidate based on our platform that we may develop, could fail to meet required standards, our regulatory approvals could be delayed, denied or revoked, and commercialization of one or more of our products may be delayed or foregone. Manufacturing processes that are used to produce the smaller quantities of HOCl- based products needed for clinical tests and current commercial sales may not be successfully scaled up to allow production of significant commercial quantities. Any failure to manufacture our products to required standards on a commercial scale could result in reduced revenues, delays in generating revenue and increased costs. Our competitive position depends on our ability to protect our intellectual property and our proprietary technologies. Our ability to compete and to achieve and maintain profitability depends on our ability to protect our intellectual property and proprietary technologies. We currently rely on a combination of patents, patent applications, trademarks, trade secret laws, confidentiality agreements, license agreements and invention assignment agreements to protect our intellectual property rights. We also rely upon unpatented know- how and continuing technological innovation to develop and maintain our competitive position. These measures may not be adequate to safeguard our HOCl technology. If we do not protect our rights adequately, third parties could use our technology, and our ability to compete in the market would be reduced. Our pending patent applications and any patent applications we may file in the future may not result in issued patents, and we do not know whether any of our in- licensed patents or any additional patents that might ultimately be issued by the U. S. Patent and Trademark Office or foreign regulatory body will protect our HOCl technology. Any claims that are issued may not be sufficiently broad to prevent third parties from producing competing substitutes and may be infringed, designed around, or invalidated by third parties. Even issued patents may later be found to be invalid or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our European patent that was initially issued on May 30, 2007 was revoked by the Opposition Division of the European Patent Office in December 2009 following opposition proceedings instituted by a competitor. The degree of future protection for our proprietary rights is more uncertain in part because legal means afford only limited protection and may not adequately protect our rights, and we will not be able to ensure that: · we were the first to invent the inventions described in patent applications; · we were the first to file patent applications for inventions; · others will not independently develop similar or alternative technologies or duplicate our products without infringing our intellectual property rights; · any patents licensed or issued to us will provide us with any competitive advantages; · we will develop proprietary technologies that are patentable; or · the patents of others will not have an adverse effect on our ability to do business. The policies we use to protect our trade secrets may not be effective in preventing misappropriation of our trade secrets by others. In addition, confidentiality and invention assignment agreements executed by our employees, consultants and advisors may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosures. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property in the United States, or in foreign countries where the laws may not protect our proprietary rights as fully as in the United States. We may face intellectual property infringement claims that could be time- consuming, costly to defend and could result in our loss of significant rights and, in the case of patent infringement claims, the assessment of treble damages. On occasion, we may receive notices of claims of infringement, misappropriation, or misuse of other parties' proprietary rights. We may have disputes regarding intellectual property rights with the parties that have licensed those rights to us. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of its outcome, is expensive and time- consuming, and could divert management' s attention from our business and have a material negative effect on our business, operating results, or financial condition. In addition, the outcome of such litigation may be unpredictable. If there is a successful claim of infringement against us, we may be required to pay substantial damages, including treble damages if we were to be found to have willfully infringed a third party' s patent, to the party claiming infringement, develop non- infringing technology, stop selling our products or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non- infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, modifying our products to exclude infringing technologies could require us to seek re- approval or clearance from various regulatory bodies for our products, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our technology. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our products or using technology that contains the allegedly infringing intellectual property, which could harm our business. We could be required to indemnify third parties for alleged intellectual property infringement, which could cause us to incur significant costs. Some of our distribution agreements contain commitments to indemnify our distributors against liability arising from infringement of third- party intellectual property, such as patents. We may be required to indemnify our customers for claims made against them or to contribute to license fees they are required to pay. If we are forced to indemnify for claims or to pay license fees, our business and financial condition could be substantially harmed. Our international operations are subject to trade policies and trade agreements and unfavorable changes could harm our business. We have significant international operations in Mexico and Europe, and we manufacture products for export in Mexico. There may be changes to existing trade agreements, like the USMCA, which went to effect on July 1, 2020,

greater restrictions on free trade generally, and significant increases in tariffs on goods imported into the United States, particularly tariffs on products manufactured in Mexico, among other possible changes. Any changes to USMCA (or subsequent trade agreements) could impact our operations in countries where we manufacture or sell products or source components, or materials, which could adversely affect our operating results and our business. Our sales in international markets subject us to foreign currency exchange and other risks and costs which could harm our business. A substantial portion of our revenues are derived from outside the United States, primarily from Mexico and Europe. We anticipate that revenues from international customers will continue to represent a substantial portion of our revenues for the foreseeable future. Because we generate revenues in foreign currencies, we are subject to the effects of exchange rate fluctuations. The functional currency of our Mexican subsidiary is the Mexican Peso and the functional currency of our Netherlands subsidiary is the Euro. For the preparation of our consolidated financial statements, the financial results of our foreign subsidiaries are translated into U. S. dollars using average exchange rates during the applicable period. If the U. S. dollar appreciates against the Mexican Peso or the Euro, as applicable, the revenues we recognize from sales by our subsidiaries will be adversely impacted. Foreign exchange gains or losses as a result of exchange rate fluctuations in any given period could harm our operating results and negatively impact our revenues. Additionally, if the effective price of our products were to increase as a result of fluctuations in foreign currency exchange rates, demand for our products could decline and adversely affect our results of operations and financial condition. The markets in which we operate are highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are less expensive or more effective than any products that we may develop, our commercial opportunity may be reduced or eliminated. Our success depends, in part, upon our ability to stay at the forefront of technological change and to maintain a competitive position. We compete with large healthcare, pharmaceutical and biotechnology companies, along with smaller or early- stage companies that have collaborative arrangements with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre- clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Our competitors may: · develop and patent processes or products earlier than we will; · develop and commercialize products that are less expensive or more efficient than any products that we may develop; · obtain regulatory approvals for competing products more rapidly than we will; and · improve upon existing technological approaches or develop new or different approaches that render our technology or products obsolete or non- competitive. As a result, we may not be able to successfully commercialize any future products. The success of our research and development efforts may depend on our ability to find suitable collaborators to fully exploit our capabilities. If we are unable to establish collaborations or if these future collaborations are unsuccessful, our research and development efforts may be unsuccessful, which could adversely affect our results of operations and financial condition. An ~~important~~ element of our business strategy is to enter into collaborative or license arrangements under which we license our HOCl technology to other parties for development and commercialization. We expect to seek collaborators for our potential products because of the expense, effort and expertise required to conduct clinical trials and further develop those potential product candidates. Because collaboration arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. If we need third party assistance in identifying and negotiating one or more acceptable arrangements, it might be costly. Also, we may not have products that are desirable to other parties, or we may be unwilling to license a potential product because the party interested in it is a competitor. The terms of any arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position or for scientific, commercial or other reasons. If we are unable to establish collaborative agreements, we may not be able to develop and commercialize new products, which would adversely affect our business and our revenues. In order for any of these collaboration or license arrangements to be successful, we must first identify potential collaborators or licensees whose capabilities complement and integrate well with ours. We may rely on these arrangements for not only financial resources, but also for expertise or economies of scale that we expect to need in the future relating to clinical trials, manufacturing, sales and marketing, and for licensing technology rights. However, it is likely that we will not be able to control the amount and timing ~~or~~ **of** resources that our collaborators or licensees devote to our programs or potential products. If our collaborators or licensees prove difficult to work with, are less skilled than we originally expected, or do not devote adequate resources to the program, the relationship will not be successful. If a business combination involving a collaborator or licensee and a third party were to occur, the effect could be to diminish, terminate or cause delays in development of a potential product. If we are unable to comply with broad and complex federal and state fraud and abuse laws, including state and federal anti- kickback laws, we could face substantial penalties and our products could be excluded from government healthcare programs. We are subject to various federal and state laws pertaining to healthcare fraud and abuse, which include, among other things, " anti- kickback " laws that prohibit payments to induce the referral of products and services, and " false claims " statutes that prohibit the fraudulent billing of federal healthcare programs. Our operations are subject to the Federal Anti- Kickback Statute, a criminal statute that, subject to certain statutory exceptions, prohibits any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward a person either (i) for referring an individual for the furnishing of items or services for which payment may be made in whole or in part by a government healthcare program such as Medicare or Medicaid, or (ii) for purchasing, leasing, ordering or arranging for or recommending the purchasing, leasing or ordering of an item or service for which payment may be made under a government healthcare program. Because of the breadth of the Federal Anti- Kickback Statute, the Office of Inspector General of the U. S. Department of Health and Human Services, was authorized to adopt regulations setting forth additional exceptions to the prohibitions of the statute commonly known as " safe harbors. " If all of the elements of an applicable safe harbor are fully satisfied, an arrangement will not be subject to prosecution under the Federal Anti- Kickback Statute. In addition, if there is a change in law, regulation or administrative or judicial interpretations of these

laws, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a negative effect on our business, financial condition and results of operations. Healthcare fraud and abuse laws are complex, and even minor, inadvertent irregularities can potentially give rise to claims that a statute or regulation has been violated. The frequency of suits to enforce these laws has increased significantly in recent years and has increased the risk that a healthcare company will have to defend a false claim action, pay fines or be excluded from the Medicare, Medicaid or other federal and state healthcare programs as a result of an investigation arising out of such action. We cannot guarantee that we will not become subject to such litigation. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could harm our reputation, be costly to defend and divert management' s attention from other aspects of our business. Similarly, if the physicians or other providers or entities with which we do business are found to have violated abuse laws, they may be subject to sanctions, which could also have a negative impact on us. We may not be able to maintain sufficient product liability insurance to cover claims against us. Product liability insurance for the healthcare industry is generally expensive to the extent it is available at all. We may not be able to maintain such insurance on acceptable terms or be able to secure increased coverage if the commercialization of our products progresses, nor can we be sure that existing or future claims against us will be covered by our product liability insurance. Moreover, the existing coverage of our insurance policy or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future claims. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage and not subject to any indemnification or contribution could have a material adverse effect on our future business, financial condition, and results of operations. If any of our third- party..... results of operations and financial condition. Our ability to generate revenue will be diminished if ~~we or~~ our partners are unable to obtain acceptable prices or an adequate level of reimbursement from third- party payors, or our partners may face pricing pressure from private third- party payers, including customers, from rebates and restrictive reimbursement practices. Our partner' s ability to commercialize our products successfully will depend in part on the extent to which appropriate coverage and reimbursement levels for the cost of our products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. In the United States, governmental and private payors have limited the growth of health care costs through price regulation or controls, competitive pricing programs and drug rebate programs. There is significant uncertainty concerning third- party coverage and reimbursement of newly approved medical products. Third- party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed healthcare in the United States and the concurrent growth of organizations such as HMOs, as well as the " Affordable Care Act, " or any new healthcare laws may result in lower prices for or rejection of our products. The cost containment measures that ~~health~~ **healthcare** ~~care~~ payors and providers are instituting and the effect of any healthcare reform or changes to managed healthcare could materially and adversely affect our ability to generate revenues. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our partner' s abilities to sell our products profitably, and thus lead to decreased demand for our products and revenues for us. We were able to negotiate minimum purchase requirements in certain of our third- party distributor agreements. However, we have limited control over purchases by our distributors, to meet the minimum purchase thresholds or above the minimum purchase thresholds. Increasingly, private health insurance companies and self- insured employers have been raising co- payments required from beneficiaries and looking for other ways to shift more of the cost burden to manufacturers and patients. This cost shifting has given consumers greater control of medication choices, as they pay for a larger portion of their prescription costs and may cause consumers to favor lower cost generic alternatives to branded pharmaceuticals. Additionally, patients continue to face cost reduction pressures that may cause them to curtail their use of, or seek reimbursement for, our products, to negotiate reduced fees or other concessions or to delay payment. Third- party payors may reduce or limit reimbursement for our products in the future, such as by withdrawing their coverage policies, canceling any future contracts, reviewing and adjusting the rate of reimbursement, or imposing limitations on coverage. Any such changes could negatively impact the sales of our products by our partners, and therefore, have a material adverse effect on our revenues. Our ability to generate revenue will be diminished if ~~we or~~ our partners are unable to manage customer product substitutions for our prescription products. Similar to other pharmaceutical companies, patients are increasingly seeking lower- cost substitutes to our products. Even if our patients have a prescription for our product, the pharmacist may recommend a less expensive product even if that product is less effective or designed for conditions different from what the patient is seeking to treat. As a result, the patient may choose to abandon purchasing our prescribed product for a less expensive alternative product resulting in a lost sale for our partners. If the number of consumers substituting our products increases, it could have a material adverse effect on sales of our products by our partners, and therefore, our revenues, financial position, cash flows and results of operations. Our inability to raise additional capital on acceptable terms in the future may cause us to curtail certain operational activities, including regulatory trials, sales and marketing, and international operations, in order to reduce costs and sustain the business, and such inability would have a material adverse effect on our business and financial condition. We ~~expect capital outlays and operating expenditures to increase over the next several years as we work to expand our sales force, conduct regulatory trials, commercialize our products and expand our infrastructure. We~~ may need to raise additional capital **in the future** in order to, among other things: · increase our sales and marketing efforts to drive market adoption and address competitive developments; · sustain commercialization of our current products or new products; · acquire or license technologies; · develop new products; · expand our manufacturing capabilities; and · finance capital expenditures and our general and administrative expenses. Our present and future funding requirements will depend on many factors, including: · the level of research and development investment required to maintain and improve our technology position; · cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; · our efforts to acquire or license complementary technologies or acquire complementary businesses; · changes in product development plans needed to address any difficulties in commercialization; · competing technological and market

developments; and · changes in regulatory policies or laws that affect our operations. If we raise additional funds by issuing equity securities, it will result in dilution to our stockholders. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations or licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. A failure to obtain adequate funds may cause us to curtail certain operational activities, including regulatory trials, sales and marketing, and international operations, in order to reduce costs and sustain our business, and would have a material adverse effect on our business and financial condition. Our information technology and infrastructure may be breached or attacked **, which could expose us to liability, damage our reputation, compromise our confidential information or otherwise adversely affect our business** . In the ordinary course of our business, we collect and store a limited amount of sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers, business partners, and personally identifiable information of our customers and employees, in our data centers and on our networks. The secure processing, maintenance, and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations and the services we provide to customers, and damage our reputation, and cause a loss of confidence in our products and services, which could adversely affect our business, revenues and competitive position. Our cash and cash equivalents may be exposed to failure of our banking institutions. We maintain our cash at financial institutions, in balances that exceed current FDIC insurance limits. **If** ~~On March 10, 2023, Silicon Valley Bank (" SVB ") was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation was appointed receiver of SVB. While none of our cash and cash equivalents was held at SVB, if~~ the banks where we hold deposits were to become insolvent or enter receivership, our ability to access our cash, cash equivalents and investments, including transferring funds, making payments or receiving funds, may be threatened, and this could have a material adverse effect on our business and financial condition. Risks Related to Our Common Stock The market price of our common stock may be volatile, and the value of your investment could decline significantly. The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospects. It is impossible to assure you that the market price of our shares of common stock will not fall in the future. Our operating results may fluctuate, which could cause our stock price to decrease. Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including: · demand by physicians, other medical staff and patients for our HOCl- based products **; · clinical trial results published by others in our industry and publication of results in peer-reviewed journals or the presentation at medical conferences; · the inclusion or exclusion of our HOCl- based products in large clinical trials conducted by others; · actual and anticipated fluctuations in our quarterly financial and operating results; · developments or disputes concerning our intellectual property or other proprietary rights; · issues in manufacturing our product candidates or products; · new or less expensive products and services or new technology introduced or offered by our competitors or by us** ; · reimbursement decisions by third- party payors and announcements of those decisions ~~; · clinical trial results published by others in our industry and publication of results in peer- reviewed journals or the presentation at medical conferences; · the inclusion or exclusion of our HOCl- based products in large clinical trials conducted by others; · actual and anticipated fluctuations in our quarterly financial and operating results; · developments or disputes concerning our intellectual property or other proprietary rights; · issues in manufacturing our product candidates or products; · new or less expensive products and services or new technology introduced or offered by our competitors or by us~~ ; · the development and commercialization of product enhancements; · changes in the regulatory environment; · delays in establishing new strategic relationships; · costs associated with collaborations and new product candidates; · introduction of technological innovations or new commercial products by us or our competitors; · litigation or public concern about the safety of our product candidates or products; · changes in recommendations of securities analysts or lack of analyst coverage; · failure to meet analyst expectations regarding our operating results; · additions or departures of key personnel; and · general market conditions. Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, The Nasdaq Capital Market, in general, and the market for life sciences companies, in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Anti-takeover provisions in our certificate of incorporation and bylaws and under Delaware law may make it more difficult for stockholders to change our management and may also make a takeover difficult. Our corporate documents and Delaware law contain provisions that limit the ability of stockholders to change our management and may also enable our management to resist a takeover. These provisions include: · the ability of our Board of Directors to issue and designate, without stockholder approval, the rights of up to 714, 286 shares of convertible preferred stock, which rights could be senior to those of common stock; · limitations on persons authorized to call a special meeting of stockholders; and · advance notice procedures required for

stockholders to make nominations of candidates for election as directors or to bring matters before meetings of stockholders. We are subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, prohibits " business combinations " between a publicly- held Delaware corporation and an " interested stockholder, " which is generally defined as a stockholder who became a beneficial owner of 15 % or more of a Delaware corporation' s voting stock for a three- year period following the date that such stockholder became an interested stockholder. These provisions might discourage, delay or prevent a change of control in our management. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and cause us to take other corporate actions. In addition, the existence of these provisions, together with Delaware law, might hinder or delay an attempted takeover other than through negotiations with our Board of Directors. Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock or other securities convertible into common stock. Our Restated Certificate of Incorporation, as amended, allows us to issue up to 24, 000, 000 shares of our common stock and to issue and designate, without stockholder approval, the rights of up to 714, 286 shares of preferred stock. In the event we issue additional shares of our capital stock, dilution to our stockholders could result. In addition, if we issue and designate a class of convertible preferred stock, these securities may provide for rights, preferences or privileges senior to those of holders of our common stock. Additionally, if we issue preferred stock, it may convert into common stock at a ratio of 1: 1 or greater because our Restated Certificate of Incorporation, as amended, allows us to designate a conversion ratio without limitations. Shares issuable upon the ~~conversion of warrants or preferred stock or the~~ exercise of outstanding options may substantially increase the number of shares available for sale in the public market and depress the price of our common stock. As of March 31, ~~2023~~ **2024** , we had outstanding ~~warrants exercisable for~~ **options to purchase** an aggregate of ~~104~~ **1** , ~~000~~ **032, 999** shares of our common stock at a weighted average exercise price of ~~approximately~~ $ ~~9~~ **2** . **42** ~~27 per share. We also had units convertible into 46, 000 shares of common stock at an exercise price of $ 11. 25 per unit. In addition, as of March 31, 2023, options to purchase an aggregate of 565, 000 shares of our common stock were outstanding at a weighted average exercise price of $ 8. 84~~ per share and a weighted average contractual term of 8. ~~41~~ **91** years. In addition, ~~982~~ **125** , ~~000~~ **556** shares of our common stock were available on March 31, ~~2023~~ **2024** for future option grants under our 2016 Equity Incentive Plan and our 2021 Equity Incentive Plan. To the extent any ~~of these warrants or options are exercised and any~~ additional options are granted and exercised, there will be further dilution to stockholders and investors. Until the options ~~and warrants~~ expire, these holders will have an opportunity to profit from any increase in the market price of our common stock without assuming the risks of ownership. Holders of options ~~and warrants~~ may convert or exercise these securities at a time when we could obtain additional capital on terms more favorable than those provided by the options ~~or warrants~~ . The exercise of the options ~~and warrants~~ will dilute the voting interest of the owners of presently outstanding shares by adding a substantial number of additional shares of our common stock. We have filed several registration statements with the SEC, so that substantially all of the shares of our common stock which are issuable upon the exercise of outstanding warrants and options may be sold in the public market. The sale of our common stock issued or issuable upon the exercise of the warrants and options described above, or the perception that such sales could occur, may adversely affect the market price of our common stock. ~~34~~ **Our failure to maintain compliance with Nasdaq' s continued listing requirements could result in the delisting of our common stock. On September 22, 2023, we received a letter from The Nasdaq Stock Market LLC (" Nasdaq ") indicating that we are not in compliance with Nasdaq Listing Rule 5550 (a) (2), which requires companies listed on The Nasdaq Stock Market to maintain a minimum bid price of $ 1 per share for continued listing. On March 21, 2024, we received a notice that Nasdaq had granted us an additional 180 calendar days, or until September 16, 2024, to regain compliance with the minimum closing bid price requirement for continued listing. Nasdaq' s letter has no immediate impact on the listing of our common stock, which will continue to be listed and traded on Nasdaq, subject to our compliance with the other continued listing requirements. We may regain compliance at any time during this compliance period if the minimum bid price for our common stock is at least $ 1 for a minimum of ten consecutive business days. Until Nasdaq has reached a final determination that we have regained compliance with all of the applicable continued listing requirements, there can be no assurances regarding the continued listing of our common stock or warrants on Nasdaq. The delisting of our common stock and warrants from Nasdaq would have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of its common stock as a result of that delisting would adversely affect our ability to raise capital on terms acceptable to the Company, if at all.**