Risk Factors Comparison 2025-03-26 to 2024-03-29 Form: 10-K

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

An investment in our common shares involves a significant risk of loss. You should carefully read this entire Annual Report and should give particular attention to the following risk factors. You should recognize that other significant risks may arise in the future, which we cannot reasonably foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than currently expected. There are a number of important factors that could cause our actual results to differ materially from those expressed or implied by any of our forward- looking statements in this Annual Report. These factors include, without limitation, the risk factors listed below, and other factors presented throughout this Annual Report and any other documents filed by us with the SEC and the Canadian securities regulators on SEDAR. Risks Related to Our Business We have a history of significant losses and have had limited revenues to date through the sale of our product. If we do not generate significant revenues, we will not achieve profitability. To date, we have been engaged primarily in research and development activities. We have incurred significant operating losses every year since our inception in September 1996. We reported a net loss of approximately $ ~~16~~ **0** . ~~05~~ **44** million for the year ended December 31, ~~2023~~ **2024** and reported a net loss of approximately $ ~~23~~ **16** . ~~71~~ **05** million for the year ended December 31, ~~2022~~ **2023** . At December 31, ~~2023~~ **2024** , we had an accumulated deficit of approximately $ 219. ~~2~~ **7** million. We anticipate **potentially** incurring substantial additional losses due to the need to spend substantial amounts on activities required for commercialization of PEDMARK ® in the U. S. and regulatory ~~approval~~ **approvals** of PEDMARK ® outside of the U. S., as well as **the preparation for potential** commercial launch preparation of PEDMARK ® outside of the U. S., anticipated research and development activities, and general and administrative expenses, among other factors. We may never achieve or sustain profitability on an ongoing basis. PEDMARK ® is currently our only product and there is no assurance that we will successfully develop PEDMARK ® into a commercially viable product. Since our formation in September 1996, we have engaged in research and development programs. We have recently begun to generate revenue from product sales in the United States after regulatory approval of PEDMARK ® in late 2022. PEDMARK ® is currently our only product. There can be no assurance that the research we fund and manage will lead PEDMARK ® or any future product candidate to become a commercially viable product. We have completed two- Phase 3 studies for PEDMARK ®. **PEDMARQSI has also been approved in the EU and U. K. We anticipate potential substantial regulatory review prior to the commercialization of PEDMARK ® outside of the United States, E. U. and U. K.** We anticipate substantial regulatory review prior to the commercialization of PEDMARK ® outside of the United States. We may require additional financing to obtain marketing approval of PEDMARK ® and commercialize PEDMARK ® abroad and a failure to obtain this capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts outside of the United States. Based on available resources, we believe that our cash and cash equivalents of $ ~~13~~ **26** . ~~3~~ **6** million available as of December 31, ~~2023~~ **2024** are sufficient to fund our anticipated operating and capital requirements for at least the next 12 months. Moreover, we expect to continue to incur losses for the foreseeable future as we continue our development of and seek marketing approvals for PEDMARK ® outside of the United States **, E. U. and U. K** . We may not be able to obtain additional financing in sufficient amounts or on acceptable terms when needed. If we fail to arrange for sufficient capital on a timely basis, we may be required to curtail our business activities until we can obtain adequate financing. Debt financing must be repaid regardless of whether or not we generate profits or cash flows from our business activities. Equity financing may result in dilution to existing shareholders and may involve securities that have rights, preferences, or privileges that are senior to our common shares or other securities. If we cannot raise sufficient capital when necessary, we will likely have to curtail operations and you may lose part or all of your investment. Our success depends on our ability to successfully commercialize PEDMARK ®. We are a single product company with only limited commercial experience, which makes it difficult to evaluate our current business, predict our future prospects, and forecast our financial performance and growth. We have invested a significant portion of our efforts and financial resources to date into the development and commercialization of our only product, PEDMARK ®. Our success depends on our ability to effectively commercialize PEDMARK ®, and we expect that all of our product revenues in the foreseeable future will be from sales of PEDMARK ®. Continued commercialization of PEDMARK ® is subject to many risks. Until we launched PEDMARK ®, we had never launched or commercialized a product, and there is no guarantee that we will be able to achieve profitability and **become** cash flow positive based on our sales of PEDMARK ®. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market growth potential, including by pharmaceutical companies with more resources and experience than we have. The long term commercial success of PEDMARK ® depends on the extent to which patients and physicians accept and adopt PEDMARK ® **.** For example, if the expected patient population is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to take PEDMARK ®, or if patients discontinue from use of the medication at rates that are higher than we expect, or if payers decide not to reimburse for our product, the commercial potential of PEDMARK ® will be limited. Thus, significant uncertainty remains regarding the ultimate commercial potential of PEDMARK ®. Moreover, our ability to effectively generate significant product revenue from PEDMARK ® will depend on our ability to, among other things: **26** ● educate patients and physicians successfully about efficacy expectations, side effects expectations, and how to successfully dose and titrate the medication to optimal patient benefit in order to minimize discontinuation due to perceived lack of efficacy or side effects; ~~25~~ ● educate pediatric cancer patients who will have cisplatin administration, and the physicians who treat them, as to the benefits to such patients of treatment using PEDMARK ® (in addition to the treatments they are receiving for their cancer); ● achieve and maintain compliance with regulatory requirements,

including those related to our required post- approval studies, promotion and advertising requirements; ● increase awareness for and achieve market acceptance of PEDMARK ® through our sales and marketing activities and other arrangements established for the promotion of PEDMARK ®; ● train, deploy, support, and retain a qualified field sales and marketing force; ● secure continued formulary approvals for PEDMARK ® with a substantial number of targeted payors; ● ensure that our third- party manufacturers manufacture PEDMARK ® in sufficient quantities, in compliance with requirements of the FDA and at acceptable quality and pricing levels, in order to meet commercial demand; ● ensure that our third- party manufacturers develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP regulations; ● implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms; ● ensure that our entire supply chain efficiently and consistently delivers PEDMARK ® to our customers; ● provide co- pay assistance to help qualified patients with out- of- pocket costs associated with their PEDMARK ® prescription, and / or other programs to ensure patient access to our product, educate physicians and patients about the benefits, administration and use of PEDMARK ®, and obtain acceptance of PEDMARK ® as safe and effective by patients and the medical community; ● receive adequate levels of coverage and reimbursement for PEDMARK ® from commercial health plans and governmental health programs; ● generate positive experience with our Fennec HEARS ® program in helping patients obtain access to PEDMARK ® at an acceptable patient out- of- pocket cost; ● maintain quality relationships with patient advocacy groups; ● influence the nature of publicity related to our product relative to the publicity related to our competitors' products; and ● obtain regulatory approvals for additional indications for the use of PEDMARK ® in treating other patient populations. ~~26Any~~ **27Any** disruption in our ability to generate product revenue from the sale of PEDMARK ® will have a material and adverse impact on our results of operations. If we are unable to continue to successfully commercialize PEDMARK ®, our business, results of operations and financial condition may be materially adversely affected. Our strategy is to successfully commercialize PEDMARK ® in the United States and abroad. There are risks involved both with maintaining our own sales and marketing capabilities, and with entering into arrangements with third parties to perform these services. For example, any efforts to maintain a direct sales and marketing organization are subject to numerous risks, including: ● the expense and time required to recruit, retain, and motivate members of the sales force; ● our inability to recruit, retain or motivate adequate numbers of effective marketing personnel and partner marketing agencies; ● the inability to provide adequate training to sales and marketing personnel; ● the expense and time required to monitor regulatory compliance; ● the inability of sales personnel to obtain access to physicians or convince adequate numbers of physicians to prescribe any product; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. Similarly, as we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability associated with any product revenue may be lower than if we were to market and sell any product that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us. We may 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 product effectively. Moreover, we may be negatively impacted by other factors outside of our control relating to such third parties, including, but not limited to, their inability to comply with regulatory requirements. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product. Finally, because we are using a very small group of exclusive specialty pharmacies to distribute our product, if the organizations that we work with to deliver our drug do not perform in a lawful manner or have issues unrelated to our business, our business could be adversely affected. Our business is subject to substantial competition. The biotechnology and pharmaceutical industries are highly competitive. Many of our competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approvals of products and manufacturing and marketing products than we have. We compete against pharmaceutical companies that are developing or currently marketing therapies that will compete with us. In addition, we compete against biotechnology companies, universities, government agencies, and other research institutions in the development of drug products. Our business could be negatively impacted if our competitors' present or future offerings are more effective, safer or less expensive than ours, or more readily accepted by regulators, healthcare providers or third- party payors. Further, we may also compete with respect to manufacturing efficiency and marketing capabilities. For all of these reasons, we may not be able to compete successfully. ~~27If~~ **28If** we do not maintain current or enter into new collaborations with other companies, we might not successfully develop our product or generate sufficient revenues to expand our business. We currently rely on scientific and research and development collaboration arrangements with academic institutions and other third- party collaborators, including an exclusive worldwide license from OHSU for PEDMARK ® ~~. We also rely on collaborators for testing PEDMARK ®, including SIOPEL and the Children' s Oncology Group~~ . The agreements with OHSU are terminable by either party in the event of an uncured breach by the other party. We may also terminate our agreement with OHSU at any time upon prior written notice of specified durations to OHSU. Termination of any of our collaborative arrangements could materially adversely affect our business. For example, if we are unable to make the necessary payments under these agreements, the licensor might terminate the agreement which might have a material adverse impact. In addition, our collaborators might not perform as agreed in the future. Since we conduct a significant portion of our research and development through collaborations, our success may depend significantly on the performance of such collaborators, as well as any future collaborators. Collaborators might not commit sufficient resources to the research and development or commercialization of our product candidate. Economic or technological advantages of products being developed by others, among other factors, could lead our collaborators to pursue other products or technologies in preference to those being developed in collaboration with us. There is a risk of dispute with respect to ownership of technology developed under any collaboration. Our management of any collaboration will require significant time and effort as well as an effective allocation of resources. We may not be able to simultaneously manage a large number of collaborations. Any of these negative impacts on our current or future collaborations

could have a material adverse effect on our business and results of operations. Regulatory approval of our product is time-consuming, expensive and uncertain, and could result in unexpectedly high expenses and delay our ability to sell our product in the U. S. and abroad. Development, manufacture and marketing of our product is subject to extensive regulation by governmental authorities in the United States and other countries. This regulation could require us to incur significant unexpected expenses or delay or limit our ability to sell our product abroad. Our clinical studies might be delayed or halted, or additional studies might be required, for various reasons, including: ● there is a lack of sufficient funding; ● the drug is not effective; ● patients experience severe side effects during treatment; ● appropriate patients do not enroll in the studies at the rate expected; ● drug supplies are not sufficient to treat the patients in the studies; or ● we decide to modify the drug during testing. If regulatory approval of our product is granted outside of the United States, it will be limited to those indications for which the product has been shown to be safe and effective, as demonstrated to the satisfaction of the FDA and foreign regulators through clinical studies. Furthermore, approval abroad might entail ongoing requirements for post- marketing studies. Even if regulatory approval is obtained outside for the United States, labeling and promotional activities are subject to continual scrutiny by the FDA and state and foreign regulatory agencies and, in some circumstances, the Federal Trade Commission. FDA enforcement policy prohibits the marketing of approved products for unapproved, or off- label, uses. These regulations and the FDA' s interpretation of them might impair our ability to effectively market our product. We and our third- party manufacturers are also required to comply with the applicable cGMP regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, manufacturing facilities, which we outsource to third parties, must be approved by the FDA before they can be used to manufacture our product, and they are subject to additional FDA inspection. The **complete response letters (“** CRL **”)** that we received ~~28from~~ -- **from** the FDA in August 2020 and in November 2021 as a result of deficiencies in the ~~third~~ **29third** - party manufacturing facility that manufactures PEDMARK ® on our behalf is a specific example of the risks associated with our third- party manufacturers. If we fail to comply with any of the FDA' s continuing regulations, or any other regulations under which we may be required to comply outside of the United States, we could be subject to reputational harm and sanctions, including: ● delays, warning letters and fines; ● product recalls or seizures and injunctions on sales; ● refusal of the FDA, or other regulators, to review pending applications; ● total or partial suspension of production; ● withdrawals of previously approved marketing applications; and ● civil penalties and criminal prosecutions. In addition, identification of side effects after a drug is on the market or the occurrence of manufacturing problems could cause subsequent withdrawal of approval, reformulation of the drug, additional testing or changes in labeling of the product. If our licenses to proprietary technology owned by others are terminated or expire, we may suffer increased development costs and delays, and we may not be able to successfully commercialize our product. The development of our drug and the manufacture and sale of any products that we develop will involve the use of processes, products and information, some of the rights to which are owned by others. PEDMARK ® is licensed under agreements with OHSU. Although we have obtained licenses or rights with regard to the use of certain processes, products and information, the licenses or rights could be terminated or expire during critical periods and we may not be able to obtain, on favorable terms or at all, licenses or other rights that may be required. Some of these licenses provide for limited periods of exclusivity that may be extended only with the consent of the licensor, which may not be granted. If we are unable to adequately protect or maintain our patents and licenses related to our product, or if we infringe upon the intellectual property rights of others, we may not be able to successfully maintain commercial status of our product. The value of our product will depend in part upon our ability, and those of our collaborators, to obtain patent protection or licenses to patents, maintain trade secret protection and operate without infringing on the rights of third parties. Although we have successfully pursued patent applications in the past, it is possible that: ● some or all of our pending patent applications, or those we have licensed, may not be allowed; ● proprietary products or processes that we develop in the future may not be patentable; ● any issued patents that we own or license may not provide us with any competitive advantages or may be successfully challenged by third parties; or ● the patents of others may have an adverse effect on our ability to do business. It is not possible for us to be certain that we are the original and first creator of inventions encompassed by our pending patent applications or that we were the first to file patent applications for any such inventions. Further, any of our patents, once issued, may be declared by a court to be invalid or unenforceable. ~~29PEDMARK~~ **30PEDMARK** ® is currently protected by ~~three~~ **six** patents owned by us that expires in 2039. Further, patents are currently pending in the United States and other territories. In addition, periods of marketing exclusivity for PEDMARK ® have been granted in the United States under orphan drug exclusivity and in Europe under PUMA. We may be required to obtain licenses under patents or other proprietary rights of third parties, but the extent to which we may wish or need to do so is unknown. Any such licenses may not be available on terms acceptable to us or at all. If such licenses are obtained, it is likely they would be royalty bearing, which would reduce our future income, if any. If licenses cannot be obtained on an economical basis, we could suffer delays in market introduction of planned products or their introduction could be prevented, in some cases after the expenditure of substantial funds. If we do not obtain such licenses, we would have to attempt to design around patents of third parties, potentially causing increased costs and delays in product development and introduction or precluding us from developing, manufacturing or selling our planned products, or our ability to develop, manufacture or sell products requiring such licenses could be foreclosed. Litigation may also be necessary to enforce or defend patents issued or licensed to us or our collaborators or to determine the scope and validity of a third party' s proprietary rights. By example we have outstanding litigation against CIPLA **, as described elsewhere in this Annual Report** . We could incur substantial costs if litigation is required to defend ourselves in patent suits brought by third parties, if we participate in patent suits brought against or initiated by our collaborators, or if we initiate such suits. We might not prevail in any such action. An adverse outcome in litigation or an interference to determine priority or other proceeding in a court or patent office could subject us to significant liabilities, require disputed rights to be licensed from other parties or require us or our collaborators to cease using certain technology or products. Any of these events would likely have a material adverse effect on our business, financial condition and results of operations.

Much of our technological know- how that is not patentable may constitute trade secrets. Our confidentiality agreements might not provide for meaningful protection of our trade secrets, know- how or other proprietary information in the event of any unauthorized use or disclosure of information. In addition, others may independently develop or obtain similar technology and may be able to market competing products and obtain regulatory approval through a showing of equivalency to our product that has obtained regulatory approvals, without being required to undertake the same lengthy and expensive clinical studies that we would have already completed. If our third- party manufacturers breach or terminate their agreements with us, or if we are unable to secure arrangements with third party manufacturers on acceptable terms as needed in the future, we may suffer significant production delays and additional costs. We have little experience manufacturing products and do not currently have the resources to manufacture any products that we may develop. We currently have agreements with contract manufacturers for clinical supplies of PEDMARK ®, including drug substance providers and drug product suppliers, but they might not perform as agreed in the future or may terminate our agreements with them before the end of the required term. Significant additional time and expense would be required to effect a transition to a new contract manufacturer. We plan to continue to rely on contract manufacturers for the foreseeable future to produce quantities of products and substances necessary for research and development, preclinical trials, human clinical trials and product commercialization, and to perform their obligations in a timely manner and in accordance with applicable government regulations. If we develop any product with commercial potential, we will need to develop the facilities to independently manufacture such product or products or secure arrangements with third parties to manufacture them. We may not be able to independently develop manufacturing capabilities or obtain favorable terms for the manufacture of our product. While we intend to contract for the commercial manufacture of our product, we may not be able to identify and qualify contractors or obtain favorable contracting terms. We or our contract manufacturers may also fail to meet required manufacturing standards, which could result in delays or failures in product delivery, increased costs, injury or death to patients, product recalls or withdrawals and other problems that could significantly hurt our business. The CRLs that we received from the FDA in August 2020 and November 2021 as a result of deficiencies in the third- party manufacturing facility that ~~manufactures~~ **manufactured** PEDMARK ® on our behalf is a specific example of the risks associated with our third- party manufacturers. We intend to maintain a second source for back- up commercial manufacturing, wherever feasible. However, if a replacement to our future internal or contract manufacturers were required, the ability to establish second-sourcing or find a replacement manufacturer may be difficult due to the lead times generally required to manufacture drugs and the need for FDA compliance inspections and approvals of any replacement manufacturer, all of which factors could result in production ~~30delays~~ **31delays** and additional commercialization costs. Such lead times would vary based on the situation but might be twelve months or longer. We conduct our business internationally and are subject to laws and regulations of several countries which may affect our ability to access regulatory agencies and may affect the enforceability and value of our licenses. We have conducted clinical trials in the United States, Canada, Europe and the Pacific Rim and intend to, or may, conduct future clinical trials in these and other jurisdictions. There can be no assurance that any sovereign government will not establish laws or regulations that will be deleterious to our interests. There is no assurance that we, as a British Columbia corporation, will continue to have access to the regulatory agencies in any jurisdiction where we might want to conduct clinical trials or obtain regulatory approval, and we might not be able to enforce our licenses or patent rights in foreign jurisdictions. Foreign exchange controls may have a material adverse effect on our business and financial condition, since such controls may limit our ability to flow funds into or out of a particular country to meet obligations under licenses, clinical trial agreements or other collaborations. Our cash invested in money market funds might be subject to loss. Even though we believe we take a conservative approach to investing our funds, the nature of financial markets exposes us to investment risk, including the risks that the value and liquidity of our money market investments (the amounts of which substantially exceed the $ 250, 000 amount insured by the FDIC) could deteriorate significantly and the issuers of the investments we hold could be subject to credit rating downgrades. While we have not experienced any loss or write down of our money market investments in the past, we cannot guarantee that such losses will not occur in future periods. With the clinical development process successfully completed in the United States, our ability to derive further revenues from the sale of PEDMARK ® will depend upon our obtaining foreign regulatory approvals, which are subject to a number of unique risks and uncertainties. Even if we are able to demonstrate the safety and efficacy of our product in clinical trials abroad, if we fail to gain timely approval to commercialize PEDMARK ® from foreign regulatory authorities, we will be unable to generate the revenues we will need to build our business. Regulatory authorities in other countries may delay, limit or deny approval of PEDMARK ® for various reasons. For example, such authorities may disagree with the design, scope or implementation of our clinical trials; or with our interpretation of data from our preclinical studies or clinical trials; or may otherwise take the position that PEDMARK ® fails to meet the requirements and standards for regulatory approval. During the course of review, foreign regulatory bodies may request or require additional preclinical, clinical, chemistry, manufacturing, and control (“ CMC ”), or other data and information, and the development and provision of these data and information may be time consuming and expensive. Regulatory approvals may not be granted on a timely basis, if at all, and even if and when they are granted, they may not cover all the indications for which we seek approval. Further, while we may develop a product with the intention of addressing a large, unmet medical need, the foreign regulatory bodies may only approve the use of the drug for indications affecting a relatively small number of patients, thus greatly reducing the market size and our potential revenues. The approvals may also contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use, which could further narrow the size of the market. In certain countries, even if the health regulatory authorities approve a drug, it cannot be marketed until pricing for the drug is also approved. Finally, even after approval can be obtained, we may be required to recall or withdraw a product as a result of newly discovered safety or efficacy concerns, either of which would have a materially adverse effect on our business and results of operations. We have been in the past and may in the future be the target of securities litigation, which may be costly and time- consuming to defend. Following periods of market volatility in the price of a company’ s securities or the reporting of unfavorable news, security purchasers have often instituted

class action litigation. This risk is especially relevant for us because pharmaceutical companies like us have experienced significant stock price volatility in recent years. Specifically, we were named in putative securities class action complaints as a result of the decline in our stock price following the August ~~10,~~ 2020 announcement that we had received a CRL from the FDA regarding our NDA for PEDMARK ® and as result of the decline in our stock price following the November ~~29,~~ 2021 announcement that we expected to receive another CRL from the ~~31FDA~~ -- **FDA** ~~regarding~~ **32regarding** our NDA for PEDMARK ®. Both of these cases have been dismissed and closed. Our insurance coverage may be insufficient to cover all legal fees, judgments or settlements. If the outcome of any such litigation is unfavorable, it could result in us paying significant damages or settlement payments, which could have a material adverse effect on our financial condition. We have only recently transitioned from a development stage biopharmaceutical company to a commercial stage biopharmaceutical company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability. Other than the FDA approval for PEDMARK ® received in the United States in September 2022 and in the European Commission in June 2023 of PEDMARQSI ®, we have no other product candidates in the development stage. We have only recently demonstrated our ability, or our ability to arrange for a third party, to manufacture a commercial scale medicine and conduct the sales and marketing activities necessary to commercialize a product. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had more experience commercializing PEDMARK ®. In addition, as a relatively new commercial stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To be profitable, we will need to continue to successfully transition from a company with a research and development focus to a company capable of supporting commercial activities. Ultimately, we may not be successful in such a transition. There are limitations on the liability of our directors, and we may have to indemnify our officers and directors in certain instances. Our articles limit, to the maximum extent permitted under British Columbia law, the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors. Our articles provide that we will indemnify our officers and directors and may indemnify our employees and other agents to the fullest extent permitted by law. ~~These provisions may be in some respects broader than the specific indemnification provisions under British Columbia law.~~ The indemnification provisions may require us, among other things, to indemnify such officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers (other than liabilities arising ~~from willful~~ **in circumstances where the officer or director did not act honestly and in good faith with a view to the best interests of the company or the associated corporation, as the case may be, or in the case of a proceeding other than a civil proceeding, if the officer or director did not have reasonable grounds for believing that the eligible party' s** ~~misconduct~~ --- **conduct in respect** of ~~a culpable nature~~ **which the proceeding was brought was lawful**), to advance their expenses incurred as a result of certain proceedings against them as to which they could be indemnified and to obtain directors' and officers' insurance. We believe that our limitation of officer and director liability assists us to attract and retain qualified employees and directors. However, in the event an officer, a director or the board of directors commits an act that may legally be indemnified under British Columbia law, we will be responsible to pay for such officer (s) or director (s) legal defense and potentially any damages resulting there from. Furthermore, the limitation on director liability may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders from instituting litigation against directors for breach of their fiduciary duties, even though such an action, if successful, might benefit our stockholders and us. Given the difficult environment and potential for incurring liabilities currently facing directors of publicly- held corporations, we believe that director indemnification is in our and our stockholders' best interests because it enhances our ability to attract and retain highly qualified directors and reduce a possible deterrent to entrepreneurial decision- making. Nevertheless, limitations of director liability may be viewed as limiting the rights of stockholders, and the broad scope of the indemnification provisions contained in **articles** ~~our certificate of incorporation~~ and bylaws could result in increased expenses. Our board of directors believes, however, that these provisions will provide a better balancing of the legal obligations of, and protections for, directors and will contribute positively to the quality and stability of our corporate governance. **We believe** ~~Our board of directors has concluded~~ that the benefit to stockholders of improved corporate governance outweighs any possible adverse effects on stockholders of reducing the exposure of directors to liability and broadened indemnification rights. ~~Our~~ **33Our** business and operations could be adversely affected by the effects of health epidemics, like the recent COVID- 19 pandemic. Future health epidemics may affect the operations of government entities, such as the FDA, as well as contract research organizations, third- party manufacturers, and other third- parties upon whom we rely. The extent of the impact on our operations depends in part on the time these restrictions remain in place, and whether restrictions are reinstated as a result ~~32of~~ **of** rising cases. These and similar disruptions in our operations could negatively impact our business, operating results and financial condition. Possible effects may include, but are not limited to, disruption to our product launch outside the United States, which includes the ability of sales reps to communicate with oncologists, absenteeism in our labor workforce, unavailability of products and supplies used in operations, and a decline in value of our assets, including inventories, property and equipment, and marketable securities ~~. The global pandemic of COVID- 19, and the ultimate impact of the COVID- 19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full impact of potential delays or effects on our business, our clinical trials, our ability to access the capital markets, or supply chains or on the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID- 19 situation closely~~ . Natural disasters, epidemic or pandemic disease outbreaks, trade wars, political unrest or other events could disrupt our business or operations or those of our development partners, manufacturers, regulators or other third parties with whom we conduct business now or in the future. A wide variety of events beyond our control, including natural disasters, epidemic or pandemic disease outbreaks (such as the COVID- 19 pandemic), trade wars, political unrest or other events, could disrupt our business or operations or those of our manufacturers, regulatory authorities, or other third parties with whom we conduct business. These events may cause businesses and government agencies to be shut down, supply chains to be interrupted, slowed, or rendered inoperable, and

individuals to become ill, quarantined, or otherwise unable to work and / or travel due to health reasons or governmental restrictions. These limitations could negatively affect our business operations and continuity, and could negatively impact our development timelines and ability to timely perform basic business functions, including, without limitation, making SEC filings and preparing financial reports. If our operations or those of third parties with whom we conduct business are impaired or curtailed as a result of these events, the development and commercialization of our product and product candidate could be impaired or halted, which could have a material adverse impact on our business. Because the target patient population for PEDMARK ® is small, we must achieve significant market share and obtain relatively high per- patient prices for our product to achieve meaningful gross margins. PEDMARK ® targets a small patient population. A key component of the successful commercialization of a drug product for these indications includes identification of patients and a targeted prescriber base for the drug product. Due to small patient populations, we believe that we would need to have significant market penetration to achieve meaningful revenues and identifying patients and targeting the prescriber base are key to achieving significant market penetration. Typically, drugs for conditions with small prevalence have higher prices in order to generate a return on investment, and as a result, the per- patient prices at which we sell PEDMARK ® are relatively high in order for us to generate an appropriate return for the investment in these product development programs and achieve meaningful gross margins, and high per patient prices could drive physicians to seek out compounding pharmacies to provide compounded sodium thiosulfate to fill their prescriptions rather than PEDMARK ®, thereby lowering the PEDMARK ® market share or penetration in the market. There can be no assurance that we will be successful in achieving a sufficient degree of market penetration and / or obtaining or maintaining high per- patient prices for PEDMARK ® for a small patient populations. Further, even if we obtain significant market share for PEDMARK ® **,** because the potential target populations are very small, we may not be able to obtain profitability despite obtaining such significant market share. We face a risk of product liability claims and may not be able to obtain adequate insurance. Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture, and / or sale of our drug ~~products~~ **product** . Patients have received substantial damage awards in some jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of drug products used in clinical trials or after FDA approval. Liability claims may be expensive to defend and may result in large judgments against us. We currently carry liability insurance that we believe to be adequate. Our insurance may not reimburse us for certain claims or the coverage may not be sufficient to cover claims made against us. We cannot predict all of the possible harms or side effects that may result from the use of our ~~current~~ drug ~~candidates~~ **product** , or any potential future products we may acquire and use in clinical trials or after FDA approval and, therefore, the amount of insurance coverage we currently hold may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our product, our liability could exceed our ability to pay the liability. Whether or not we are ultimately successful in any adverse litigation, such litigation could ~~33consume~~ **consume** substantial ~~amounts~~ **34amounts** of our financial and managerial resources, all of which could have a material adverse effect on our business, financial condition, results of operations, prospects and stock price. Business or economic disruptions or global health concerns could seriously harm our development efforts and increase our costs and expenses. Broad- based business or economic disruptions could adversely affect our ongoing or planned research and development activities. Global health concerns, such as the COVID- 19 pandemic, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. It is also possible that global health concerns such as the COVID- 19 pandemic could disproportionately impact the hospitals and clinical sites in which we conduct any of our clinical trials, which could have a material adverse effect on our business and our results of operation and financial condition. **We have entered into, and may in the future enter into, strategic transactions for the research, development and commercialization of PEDMARK. If any of these transactions are not successful, then we may not be able to capitalize on the market potential of such product candidates. Further, we may not be able to enter into future transactions on acceptable terms, if at all, which could adversely affect our ability to develop and commercialize our potential future product candidates and former lead product candidate, impact our cash position, increase our expense, and present significant distractions to our management. We have entered into, and may enter into in the future, strategic transactions, such as out- licensing of product candidates or technologies. For example, in March 2024, we entered into a collaboration and license agreement with Norgine. Our ability to generate revenue from any of our strategic transactions will depend on our partners' abilities to successfully perform the functions assigned to them in these transactions. We cannot predict the success of any of our strategic transactions. We also intend to evaluate and, if strategically attractive, seek to enter into additional collaborations in the future, including with biotechnology or biopharmaceutical companies or hospitals. The competition for partners is intense, and the negotiation process is time- consuming and complex. If we are not able to enter into strategic transactions, we may not have access to required liquidity or expertise to further develop our potential future product candidates or our discovery platform. Any existing or potential future collaboration or other strategic transaction may require us to incur non- recurring or other charges, increase our near- and long- term expenditures and pose significant integration or implementation challenges or disrupt our management or business. We may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of such acquisitions or collaborations. In addition, any new collaboration that we enter into may be on terms that are not optimal for us.** Risks Related to the Clinical Development and Marketing Approval of Our Product outside the United StatesThe marketing approval processes of foreign authorities are lengthy, time- consuming and inherently unpredictable, and if

we are ultimately unable to obtain marketing approval for our product abroad, our business will be substantially harmed. Our current product has gained marketing approval for sale in the United States and in the European Commission, and we cannot guarantee that we will ever have regulatory approval outside the United States and European Commission. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our product candidate in abroad a timely manner. We cannot commercialize our product ~~candidate~~ **35candidate** outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Our product could fail to receive marketing approval for many reasons, including the following: ● FDA comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; ● FDA comparable foreign regulatory authorities may find the human subject protections for our clinical trials inadequate and place a clinical hold on an IND at the time of its submission precluding commencement of any trials or a clinical hold on one or more clinical trials at any time during the conduct of our clinical trials; ● we may be unable to demonstrate to the satisfaction of the FDA comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; ● the results of clinical trials may not meet the level of statistical significance required by the FDA comparable foreign regulatory authorities for approval; ● we may be unable to demonstrate that a product' s clinical and other benefits outweigh its safety risks; ● FDA comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; ● the data collected from clinical trials of our product may not be sufficient to obtain marketing approval outside of the United States; ● FDA comparable foreign regulatory authorities may find inadequate the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies (for example, see the discussion elsewhere concerning the CRLs we received from the FDA in August 2020 and November 2021); ~~and~~**34** -- **and** ● the approval policies or regulations of the FDA comparable foreign regulatory authorities may significantly change in a manner that would delay marketing approval. Before obtaining marketing approval for the commercial sale of any drug product for a target indication, we must demonstrate in preclinical studies and well- controlled clinical trials and, with respect to approval outside the United States, to the satisfaction of the foreign regulatory authorities, that the product is safe and effective for its intended use and that the manufacturing facilities, processes, and controls are adequate to preserve the drug' s identity, strength, quality and purity. In September 2022, we obtained approval of our NDA from the FDA. An NDA must include extensive preclinical and clinical data and supporting information to establish the product' s safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing, and controls for the product. After the submission of an NDA, but before approval of the NDA, the manufacturing facilities used to manufacture a product candidate generally must be inspected by the FDA to ensure compliance with the applicable cGMP requirements (for example, see the discussion elsewhere concerning the CRL we received from the FDA in August, 2020). The FDA and the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities, may also inspect our clinical trial sites and audit clinical study data to ensure that our studies are properly conducted in accordance with the IND regulations, human subject protection regulations, cGCP. In June 2023, we obtained approval for PEDMARQSI ® in the European Union **and in October 2023 in the U. K** . Regulatory authorities outside of the United States, such as in Europe and Japan and in emerging markets, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidate. Clinical trials conducted in one country may not be accepted or the results may not be found adequate by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on our ability to obtain approval in a different jurisdiction. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. ~~Seeking~~ **36Seeking** foreign regulatory approval could require additional non- clinical studies or clinical trials, which could be costly and time- consuming. Foreign regulatory approval may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. The process to develop, obtain marketing approval for, and commercialize product candidates is long, complex and costly, both inside and outside of the United States, and approval is never guaranteed. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. Even if our product were to successfully obtain approval from regulatory authorities outside the United States, any such approval might significantly limit the approved indications for use, including more limited patient populations, require that precautions, warnings or contraindications be included on the product labeling, including black box warnings, require expensive and time- consuming post- approval clinical studies, risk evaluation and mitigation strategies or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that we may make, which may impede the successful commercialization of our product candidate. Following any approval for commercial sale of our product candidate, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, may require new studies and will be subject to additional FDA notification, or review and approval. Also, marketing approval for any of our product may be withdrawn. If we are unable to obtain marketing approval for our product in one or more jurisdictions, or any approval contains significant limitations, our ability to market to our full target market will be reduced and our ability to realize the full market potential of our product will be impaired. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue or complete the development of any future product candidates. ~~35Now~~ -- **Now** that we have achieved marketing approval for our product in the United States, it will be subject to ongoing obligations and continued regulatory review, which may result in

significant additional expense. Our product could be subject to labeling and other restrictions, and we may be subject to penalties and legal sanctions if we fail to comply with regulatory requirements or experience unanticipated problems with our approved product. Now that the FDA has approved our product, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP regulations and cGCP for any clinical trials that we conduct post- approval. Any marketing approvals that we receive for our product candidate may also be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy. Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, or failure to comply with regulatory requirements, or evidence of acts that raise questions about the integrity of data supporting the product approval, may result in, among other things: ● restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; ● fines, warning letters, or holds on clinical trials; ● refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals; ● product seizure or detention, or refusal to permit the import or export of products; and ● injunctions or the imposition of civil or criminal penalties. ~~The~~ **37The** FDA' s and foreign regulatory agencies policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing approval, manufacturing or commercialization of our product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or we are not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. Agencies like the FDA and national competition regulators in European countries regulate the promotion and uses of drugs not consistent with approved product labeling requirements. If we are found to have improperly promoted PEDMARK ® for uses beyond those that are approved, we may become subject to significant liability. Regulatory authorities like the FDA and national competition laws in Europe strictly regulate the promotional claims that may be made about prescription products, such as PEDMARK ®. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign regulatory authorities as reflected in the product' s approved labeling, known as " off- label " use, nor may it be promoted prior to obtaining marketing approval. If we receive marketing approval for our product for our proposed indications, physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved label if the physicians personally believe in their professional medical judgment it could be used in such manner. Although physicians may prescribe legally available drugs for off- label uses, manufacturers may not market or promote such off- label uses. In addition, the FDA requires that promotional claims not be " false or misleading " as such terms are defined in the FDA' s regulations. For example, the FDA requires substantial evidence, which generally consists of two adequate and well- controlled head- to- head clinical trials, for a company to make a claim that its product is superior to another product in terms of safety or effectiveness. Generally, unless we perform clinical trials meeting that standard comparing our product ~~36to~~ **to** competitive products and these claims are approved in our product labeling, we will not be able promote our product as superior to other products. If we are found to have made such claims, we may become subject to significant liability. In the United States, the federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in improper promotion. The FDA has also requested that companies enter into consent decrees or corporate integrity agreements. The FDA could also seek permanent injunctions under which specified promotional conduct is monitored, changed or curtailed. Our current and future relationships with healthcare professionals, investigators, consultants, collaborators, actual customers, potential customers and third- party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to sanctions. Healthcare providers, physicians and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of our drug post- marketing approval. Our current and future arrangements with healthcare professionals, investigators, consultants, collaborators, actual customers, potential customers and third- party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute PEDMARK ®. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the U. S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid; ● federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal ~~government~~ **38government** , including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a

federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent; ● the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private), knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ● the federal Open Payments program, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, and its ~~37implementing~~ -- **implementing** regulations, which imposed annual reporting requirements for manufacturers of drugs, devices, biologicals and medical supplies for certain payments and " transfers of value " provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, where failure to submit timely, accurately and completely the required information for all covered payments, transfers of value and ownership or investment interests may result in civil monetary penalties; and ● analogous state and foreign laws, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Further, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti- Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our current and future collaborators, if any, are found not to be in compliance with applicable laws, those persons or entities ~~may~~ **39may** be subject to criminal, civil or administrative sanctions, including exclusion from participation in government healthcare programs, which could also affect our business. The impact of recent healthcare reform legislation and other changes in the healthcare industry and healthcare spending on us is currently unknown and may adversely affect our business model. In the United States and some foreign jurisdictions, legislative and regulatory changes and proposed changes regarding the healthcare system could prevent or delay marketing approval of PEDMARK ®, restrict or regulate post- approval activities and affect our ability to profitably sell PEDMARK ®. Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws and judicial decisions, or new interpretations of existing laws or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, financial condition, results of operations and prospects. There is significant interest in promoting healthcare reform. Among other things, healthcare reform may contain provisions that may reduce the profitability of drug products, including, for example, revising the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, extending the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans, imposing mandatory discounts for certain Medicare Part D beneficiaries, and subjecting drug manufacturers to payment of an annual fee. We expect that healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue or commercialize our drugs. ~~38It~~ **It** is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect: ● the demand for our product; ● our ability to set a price that we believe is fair for our product; ● our ability to

obtain coverage and reimbursement approval for our product; ● our ability to generate revenues and achieve or maintain profitability; and ● the level of taxes that we are required to pay. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition or results of operations. Our research and development activities and our third- party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third- party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot ~~guarantee~~ **40guarantee** that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Our employees, sales agents and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of fraud or other misconduct by our employees, sales agents or consultants. Misconduct could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. ~~39Risks~~ -- **Risks** Related to Commercialization of Our ProductAfter regulatory approvals in the United States, European Union and other territories, the commercial success of our product will depend on market awareness and acceptance of our product. After obtaining marketing approval for PEDMARK ®, it may not gain market acceptance among physicians, key opinion leaders, healthcare payors, patients and the medical community. Market acceptance of PEDMARK ® depends on a number of factors, including: ● the timing of market introduction; ● its efficacy and safety, as demonstrated in clinical trials; ● the clinical indications for which it is approved, and the label approved by regulatory authorities for use with the product, including any precautions, warnings or contraindications that may be required on the label; ● acceptance by physicians, key opinion leaders and patients of PEDMARK ® as a safe and effective treatment; ● the cost, safety and efficacy of treatment in relation to alternative treatments; ● the availability of coverage and adequate reimbursement and pricing by third- party payors and government authorities; ● the number and clinical profile of competing products; ● the growth of drug markets in our various indications; ● relative convenience and ease of administration; ● marketing and distribution support; **41** ● the prevalence and severity of adverse side effects; and ● the effectiveness of our sales and marketing efforts. Market acceptance is critical to our ability to generate revenue. PEDMARK ®, may be accepted in only limited capacities or not at all. If PEDMARK ® is not accepted by the market to the extent that we expect, we may not be able to generate revenue and our business would suffer. If the market opportunities for our product are smaller than we believe they are, then our revenues may be adversely affected, and our business may suffer. The market opportunities that our product is being developed to address are rare. Our projections of both the number of people who are administered cisplatin, as well as the subset of people who have the potential to benefit from treatment with our product, and our assumptions relating to pricing are based on estimates. Given the small number of patients that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product. Coverage and reimbursement may be limited or unavailable in certain market segments for our product, which could make it difficult for us to sell our product profitably. There is significant uncertainty related to third- party coverage and reimbursement of newly approved pharmaceuticals. Market acceptance and sales of our product will depend significantly on the availability of coverage and adequate reimbursement from third- party payors and may be affected by existing and future healthcare reform measures. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third- ~~40party~~ -- **party** payors to reimburse all or part of the associated healthcare costs. Government authorities and third- party payors, such as private health insurers, health maintenance organizations, and government payors like Medicare and Medicaid, decide which drugs they will pay for and establish reimbursement levels. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs and products. Coverage and reimbursement may not be available for PEDMARK ® and, even if coverage is provided, the level of reimbursement may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of,

PEDMARK ®. Reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is, among other things: ● a covered benefit under its health plan; ● safe, effective and medically necessary; ● appropriate for the specific patient; ● cost- effective; and ● neither experimental nor investigational. Obtaining coverage and adequate reimbursement approval for a product from a government or other third- party payor is a time consuming and costly process that could require us to conduct expensive pharmacoeconomic studies and provide supporting scientific, clinical and cost- effectiveness data for the use of our product to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and adequate reimbursement. In addition to examining the medical necessity and cost- effectiveness of new products, coverage may be limited to specific drug products on an approved list, or formulary, which might not include all of the FDA- approved drug products for a particular indication. There may also be formulary placements that result in lower reimbursement levels and higher cost- sharing borne by patients, any of which could have an adverse effect on our revenues and profits. Moreover, a third- party payor' s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third- party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate ~~return~~ **42return** on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third- party payor' s decision to cover a particular drug product does not ensure that other payors will also provide coverage for the drug product, or even if coverage is available, establish an adequate reimbursement rate. We cannot be sure that coverage or adequate reimbursement will be available for our product. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our product. In the United States, third- party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. Third- party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost- effectiveness of drug products and medical services and questioning safety and efficacy. As a result, significant uncertainty exists as to whether and how much third- party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. Additionally, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. If third- party payors do not consider our product to be cost- effective compared to other available therapies, they may not cover our product or, if they do, the level of payment may not be sufficient to allow us to sell our product at a profit. Coverage policies, third- party reimbursement rates and drug pricing regulation may change at any time, and there is the potential for significant movement in these areas in the foreseeable future. Even if favorable coverage and reimbursement status is attained for our product, less favorable coverage policies and reimbursement rates may be implemented in the future. ~~41We~~ **We** face substantial competition, which may result in others discovering, developing or commercializing products more successfully, than we do. The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are generally developing and marketing therapeutic products. Such competition may include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic companies and medical technology companies. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product for the treatment of orphan and ultra- orphan diseases for which there is a small patient population in both the United States and in all other potential markets. A drug designated an orphan drug may receive up to seven years of exclusive marketing in the United States for that indication. Many of our potential competitors have significantly greater financial, manufacturing, marketing, development, technical and human resources than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing clinical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established companies may also invest heavily to accelerate discovery and development of compounds that could make our product obsolete. As a result of all of these factors, maintaining orphan drug designation for our product is essential to our viability since our competitors may, among other things: ● have greater name and brand recognition, financial, manufacturing, marketing, development, technical and human resources; ● develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer; ● obtain quicker marketing approval; ● establish superior proprietary positions; ● have access to more manufacturing capacity as well as to more cost- effective manufacturing capacity; **43** ● implement more effective approaches to sales and marketing; or ● form more advantageous strategic alliances. Should any of these events occur, our business, financial condition, results of operations, and prospects could be materially adversely affected. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer. We believe that our ability to successfully compete will depend on our ability to maintain orphan drug designation as well as: ● achieving and maintaining compliance with regulatory requirements applicable to our business; ● the timing and scope of regulatory approvals, including labeling; ● adequate levels of reimbursement under private and governmental health insurance plans, including Medicare and Medicaid; ● our ability to protect intellectual property rights related to our product; ● our ability to commercialize and market our product; ~~42~~ ● our ability to manufacture and sell commercial quantities of our product; ● acceptance of our product by physicians, other healthcare providers and patients; and ● the cost of treatment in relation to alternative therapies. Price controls may be imposed in foreign markets, which may adversely affect our future profitability. In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and

pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of our product to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected. Rapid technological change could make our product obsolete. Pharmaceutical technologies have undergone rapid and significant change, and we expect that they will continue to do so. As a result, there is significant risk that our product may be rendered obsolete or uneconomical by new discoveries before we recover any expenses incurred in connection with their development. If our product is rendered obsolete by advancements in pharmaceutical technologies, our prospects will suffer. We face a risk of product liability claims and may not be able to obtain adequate insurance. Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture, and / or sale of our pharmaceutical product. Patients have received substantial damage awards in some jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of pharmaceutical products used in clinical trials or ~~after~~ **44after** FDA approval. Liability claims may be expensive to defend and may result in large judgments against us. We currently carry liability insurance that we believe to be adequate. However, our insurance may not reimburse us for certain claims or the coverage may not be sufficient to cover claims made against us. We cannot predict all of the possible harms or side effects that may result from the use of our drug and, therefore, the amount of insurance coverage we currently hold may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our product, our liability could exceed our ability to pay the liability. Whether or not we are ultimately successful in any adverse litigation, such litigation could consume substantial amounts of our financial and managerial resources, all of which could have a material adverse effect on our business, financial condition, results of operations, prospects and stock price. Risks Related to Government RegulationPEDMARK ® is subject to ongoing regulatory review. If we fail to comply with continuing United States and applicable foreign regulations, we could lose those approvals, and our business would be severely harmed. We are and will continue to be subject to continuing regulatory review for our product, including the review of our required nonclinical and clinical post- marketing studies, and other clinical results which are reported after our drug becomes commercially available. As greater numbers of patients use a drug following its approval, side effects and other problems may be observed after approval that were not seen or anticipated during preapproval clinical studies and trials. In addition, both we and the manufacturing facilities we use to make our product will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with us, the manufacturing facilities or our product may result in restrictions on us, the manufacturing facilities or our product, including withdrawal of our product from the market. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, ~~43suspension~~ -- **suspension** , or withdrawal of regulatory approval, product recalls and seizures, operating restrictions, and criminal prosecutions. Our product promotion and advertising are also subject to regulatory requirements and continuing regulatory review. In particular, the marketing claims we will be permitted to make in labeling or advertising regarding our product will be limited by the terms and conditions of the FDA- approved labeling and available scientific data. We must submit copies of our advertisements and promotional labeling to the FDA at the time of initial publication or dissemination. If the FDA believes these materials or statements promote our product for unapproved indications, or with unsubstantiated claims, or if we fail to provide appropriate safety related information, the FDA could allege that our promotional activities misbrand our product. Specifically, the FDA could issue an untitled letter or warning letter, which may demand, among other things, that we cease such promotional activities and issue corrective advertisements and labeling to all recipients of the misbranded materials. The FDA also could take enforcement action including seizure of allegedly misbranded product, injunction, or criminal prosecution against us and our officers or employees. If we repeatedly or deliberately fail to submit such advertisements and labeling to the agency, the FDA could withdraw our approvals. Moreover, the Department of Justice can bring civil or criminal actions against companies and executives that promote drugs or biologics for unapproved uses, based on the Federal Food, Drug, and Cosmetic Act, the False Claims Act, and other federal laws governing the marketing and reimbursement for such products under federally supported healthcare programs such as Medicare and Medicaid. Monetary penalties in such cases have often been substantial, and civil penalties can include costly mandatory compliance programs and potential exclusion of a company' s products from federal healthcare programs. Enacted and future legislation or judicial action may increase the difficulty and cost for us to commercialize PEDMARK ® In the United States, there have been a number of court cases, legislative and regulatory changes, and other potential changes relating to the healthcare system that restrict or regulate post- approval activities, which may affect our ability to profitably sell PEDMARK ® or any other drug candidates for which we obtain marketing approval. The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for drug products. The legislation expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D and introduced a reimbursement methodology based on average sales prices for Medicare Part B physician- administered drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies whereby they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, there is additional pressure to contain and reduce costs. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow ~~Medicare~~ **45Medicare** coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. These cost reduction initiatives and other provisions of the MMA could decrease the coverage and reimbursement that we receive for our product and could seriously harm our business. Manufacturers' contributions to this area, including donut hole coverage (as described below) or potential excise taxes, are increasing and are

subject to additional changes in the future. In 2010, former President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, the " Health Care Reform Law "), a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. The Health Care Reform Law, among other things, revised the definition of Average Manufacturer Price used by the Medicaid Drug Rebate Program for reporting purposes, imposed a significant annual fee on companies that manufacture or import branded prescription drug products and established an annual non- deductible fee on entities that sell branded prescription drugs or biologics to specified government programs in the United States. The Health Care Reform Law also expanded the 340B drug discount program (excluding orphan drugs), including the creation of new penalties for non- compliance and included a discount (now 70 %, on brand name drugs for Medicare Part D participants in the coverage gap, or " donut hole. " The Health Care Reform Law increased the Medicaid rebates for line extensions or reformulated drugs, which could substantially increase our Medicaid rebate rate (in effect limiting reimbursement for these patients). ~~44Beginning~~ -- **Beginning** in January 2017, former President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Health Care Reform Law or otherwise circumvent some of the requirements for health insurance mandated by the Health Care Reform Law. These actions include directing applicable federal agencies to waive, defer, grant exemptions from, or delay the implementation of any provision of the Health Care Reform Law that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, an Executive Order was signed terminating the cost sharing subsidies that reimburse insurers under the Health Care Reform Law. Several state Attorneys Generals filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Further, on June 14, 2018 the United States Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $ 12. 0 billion in Health Care Reform Law risk corridor payments to third- party payors. The effects of this gap in reimbursement on third- party payors, the viability of the Health Care Reform Law marketplace, providers, and our business, are not yet known. On December 18, 2019, the United States Court of Appeals for the Fifth Circuit ruled that the Health Care Reform Law' s individual mandate is unconstitutional but sent the matter back down to a district court to determine whether that provision can be removed from the rest of the Health Care Reform Law. On March 2, 2020, the U. S. Supreme Court agreed to review the Fifth Circuit' s ruling, and oral argument was heard on November 10, 2020. On June 17, 2021, the U. S. Supreme Court dismissed the challenge to the Health Care Reform Law in a 7- 2 decision. Additionally, in response to controversies regarding pricing of drug products, there has been a recent push to propose legislation, both on state and federal levels, that would require greater disclosure as to the reasoning behind drug prices and, in some cases, could give state or federal- level commissions the right to impose cost controls on certain drugs. These and other new provisions are likely to continue the pressure on pharmaceutical pricing, may require us to modify our business practices with healthcare practitioners, and may also increase our regulatory burdens and operating costs. In that regard, **the** President ~~Biden~~ and members of Congress in both parties have expressed concerns about high drug prices. However, whether and to what extent any such positions will result in changes of the law, and how any such changes could impact our business, cannot be determined at this time. Legislative and regulatory proposals also have been made to expand post- approval requirements, restrict sales and promotional activities for drug products, and with respect to orphan drug designation and exclusivity. In addition, increased scrutiny by the United States Congress of the FDA' s approval process may subject us to more stringent product labeling and post- marketing testing and other requirements. Delays in feedback from the FDA may affect our ability to quickly update or adjust our label in the interest of patient adherence and tolerability. We cannot predict whether other legislative changes will be adopted or how such changes would affect the pharmaceutical industry generally and specifically the commercialization of PEDMARK ®. ~~If~~ **46If** we fail to obtain or subsequently maintain orphan drug exclusivity or regulatory exclusivity for PEDMARK ®, our competitors may sell products to treat the same conditions at greatly reduced prices, and our revenues would be significantly adversely affected. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user- fee waivers. The company that first obtains FDA approval for a designated orphan drug for a given rare disease receives marketing exclusivity for use of that drug for the stated disease or condition for a period of seven years, with an additional six months of exclusivity if the product also qualifies for pediatric exclusivity. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective, a subsequent product is deemed clinically superior, or if the manufacturer is unable to deliver sufficient quantity of the drug. Because the extent and scope of patent protection for some of our drug products may be particularly limited, orphan drug designation – and ultimately, orphan drug exclusivity – is especially important for our product. For eligible drugs, we plan to rely on the orphan exclusivity period to maintain a competitive position. However, if we do not obtain orphan drug exclusivity for our drug candidates or we cannot maintain orphan exclusivity for our drug candidates, our competitors may then sell the same drug to treat the same condition and our revenues will be reduced. Also, without strong patent protection, competitors may sell a generic version upon the expiration of orphan exclusivity if our patent position is not upheld. ~~45Even~~ -- **Even** after an orphan drug is approved, the FDA can subsequently approve a drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. The FDA can discontinue orphan drug exclusivity after it has been granted if the orphan drug cannot be manufactured in sufficient quantities to meet demand. Finally, there can be no assurance that the exclusivity provisions currently in the law may not be changed in the future and the impact of any such changes (if made) on us. The orphan drug exclusivity contained in the Orphan Drug Act has been the subject of recent scrutiny from the press, from some members of Congress and from some in the medical community. There can be no assurance that the exclusivity granted in the Orphan Drug Act to orphan drugs approved by the FDA will not be modified in the future, and as to how any such change might affect

our product. Changes to the Orphan Drug Act or successful legal challenges to the FDA' s interpretation of the Orphan Drug Act may affect our ability to obtain or subsequently maintain orphan drug exclusivity or affect the scope of orphan drug exclusivity for our product. There can be no assurance whether the exclusivity provisions in the Orphan Drug Act may be changed in the future and the impact of such changes, if made on us. The orphan drug exclusivity contained in the Orphan Drug Act has been the subject of recent scrutiny from the press, from some members of Congress and from some in the medical community. Furthermore, the FDA' s interpretations of the Orphan Drug Act have been successfully challenged in court and future court decisions could continue that trend. There can be no assurance that the exclusivity granted in the Orphan Drug Act to orphan drugs approved by the FDA will not be modified in the future, and as to how any such change might affect our product, if approved. Our operations and relationships with healthcare providers, healthcare organizations, customers and third- party payors are subject to applicable anti- bribery, anti- kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Our current and future arrangements with healthcare providers, healthcare organizations, third- party payors, customers, and patients expose us to broadly applicable anti- bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our drug. In addition, we may be subject to patient data privacy and security regulation by the U. S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti- bribery and healthcare laws and regulations include the following: **47** • the Federal health care program Anti- Kickback Statute, which prohibits individuals and entities from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be imposed through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off- label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act; ~~46~~ • HIPAA, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by HITECH, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information; • the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advanced care practice nurses and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website; • the U. S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U. S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; and • certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. ~~If~~ **48If** we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our product successfully and could harm our reputation and lead to reduced acceptance of our product by the market. These enforcement actions include not only civil and criminal penalties, but also exclusion from participation in government- funded healthcare

programs, and exclusion from eligibility for the award of government contracts for our product. ~~47Efforts~~ **Efforts** to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management' s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. Risks Related to Third PartiesWe rely on third- party suppliers and other third parties for production of our product and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product. We do not currently own or operate manufacturing facilities for clinical or commercial production of our product. We lack the resources and the capability to manufacture our product on a clinical or commercial scale. Instead, we rely on, and expect to continue to rely on, third parties for the supply of raw materials and manufacture of drug supplies necessary to conduct our preclinical studies and clinical trials. Our reliance on third parties may expose us to more risk than if we were to manufacture our current product or other products ourselves. Delays in production by third parties could delay our clinical trials or have an adverse impact on any commercial activities. In addition, the fact that we are dependent on third parties for the manufacture of and formulation of our product means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. Although we oversee these activities to ensure compliance with our quality standards, budgets and timelines, we have had and will continue to have less control over the manufacturing of our product than potentially would be the case if we were to manufacture our product. Further, the third parties we deal with could have staffing difficulties, might undergo changes in priorities or may become financially distressed, which would adversely affect the manufacturing and production of our product. In addition, a third party could be acquired by, or enter into an exclusive arrangement with, one of our competitors, which would adversely affect our ability to access the formulations we require. Problems with the quality of the work of third parties may lead us to seek to terminate our working relationships and use alternative service providers. In addition, it may be very challenging, and in some cases impossible, to find replacement service providers that can develop and manufacture our drug in an acceptable manner and at an acceptable cost and on a timely basis. The sale of products containing any defects or any delays in the supply of necessary services could adversely affect our business, financial condition, results of operations, and prospects. Growth in the costs and expenses of components or raw materials may also adversely affect our business, financial condition, results of operations, and prospects. Supply sources could be interrupted from time to time and, if interrupted, supplies may not be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all. ~~We~~ **49We** plan to rely on third parties to conduct clinical trials for our product. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain marketing approval for or commercialize our product outside of the United States. Clinical trials must meet applicable foreign regulatory requirements. We do not have the ability to independently conduct clinical trials for our product abroad. We expect to rely on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories, to conduct all of our clinical trials of our product; however, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with our investigational plan and protocol. Moreover, the other foreign regulatory authorities require us to comply with IND and human subject protection regulations and cGCP standards, for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and ~~48results~~ **results** are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. Regulatory authorities enforce these cGCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third- party contractors fail to comply with applicable cGCP, the clinical data generated in our clinical trials may be deemed unreliable and the foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There is no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process abroad. There are significant requirements imposed on us and on clinical investigators who conduct clinical trials that we sponsor. Although we are responsible for selecting qualified CROs or clinical investigators, providing them with the information they need to conduct the clinical trials properly, ensuring proper monitoring of the clinical trials, and ensuring that the clinical trials are conducted in accordance with the general investigational plan and protocols contained in the IND, we cannot ensure that the CROs or clinical investigators will maintain compliance with all regulatory requirements at all times. The pharmaceutical industry has experienced cases where clinical investigators have been found to incorrectly record data, omit data, or even falsify data. We cannot ensure that the CROs or clinical investigators in our trials will not make mistakes or otherwise compromise the integrity or validity of data, any of which would have a significant negative effect on our ability to obtain marketing approval, our business, and our financial condition. We or the third parties we rely on may encounter problems in clinical trials that may cause us or the foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to manufacture sufficient quantities of materials for use in our clinical trials,

conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites, or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we or foreign regulatory agencies may suspend clinical trials of our product at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks, whether as a result of adverse events occurring in our trials or otherwise, or if we or they find deficiencies in the clinical trial process or conduct of the investigation. The foreign regulatory agencies could also require additional clinical trials before or after granting of marketing approval for our product, which would result in increased costs and significant delays in the development and commercialization of our product and could result in the withdrawal of our product from the market after obtaining marketing approval. Our failure to adequately demonstrate the safety and efficacy of our product in clinical development could delay or prevent obtaining marketing approval of the product and, after obtaining marketing approval, data from post- approval studies could result in our product being withdrawn from the market, either of which would likely have a material adverse effect on our business. **Our reliance on global distributors exposes us to risks related to nonperformance of key services, uncertainty of cash flow timing, and nonpayment for delivered goods. We depend on third- party distributors to commercialize and deliver our product in various global markets. These distributors may experience operational or financial difficulties that could result in disruptions to our supply chain, delays in product delivery, or failure to meet contractual obligations. In addition, the timing of payments from these distributors may be inconsistent, creating uncertainty in our cash flow projections and financial planning. There is also a risk that some distributors may be unable or unwilling to pay for delivered goods due to financial distress or disputes, which could result in significant losses. If our distributors fail to perform, it may have a material adverse effect on our revenue, profitability, and ability to achieve our business objectives.** ~~Risks~~ **50Risks** Related to Our Intellectual PropertyOur commercial success will rely upon the strength of our patents to exclude competition. Our commercial success will depend in large part on our ability to use patents and regulatory exclusivity to exclude others from competing with our product. The patent position of emerging pharmaceutical companies like us can be highly uncertain and involve complex legal and technical issues. Until our licensed patents are interpreted by a court, either because we have sought to enforce them against a competitor or because a competitor has preemptively challenged them, we will not know the breadth of protection that they will afford us. Our patents may not contain claims sufficiently broad to prevent others from practicing our technologies or marketing competing products. Third parties may intentionally attempt to design around our patents or design around our patents so as to compete with us without infringing our patents. Moreover, the issuance of a patent is not conclusive as to its validity or enforceability, and so our patents may be invalidated or rendered unenforceable if challenged by others. As a result of the foregoing factors, we cannot be certain how much protection from competition patent rights will provide us. ~~49Our~~ -- **Our** success will depend significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. While we are not currently aware of any third- party patents which we may infringe, there can be no assurance that we do not or will not infringe on patents held by third parties or that third parties will not claim that we have infringed on their patents. In the event that our product infringe or violate the patent or other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing or commercialization of our product. There may be patents held by others of which we are unaware that contain claims that our product or operations infringe. In addition, given the complexities and uncertainties of patent laws, there may be patents of which we are aware that we may ultimately be held to infringe, particularly if the claims of the patent are determined to be broader than we believe them to be. Adding to this uncertainty, in the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult. If a third- party claims that we infringe its patents, any of the following may occur: ● we may be required to pay substantial financial damages if a court decides that our technologies infringe a competitor' s patent, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of our product and intellectual property rights; ● a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross- licenses to our patents; and ● we may have to redesign our product so that it does not infringe others' patent rights, which may not be possible or could require substantial funds or time and require additional studies. In addition, employees, consultants, contractors and others may use the proprietary information of others in their work for us or disclose our proprietary information to others. If our employees, consultants, contractors or others disclose our data to others or use data belonging to others in connection with our business, it could lead to disputes over the ownership of inventions derived from that information or expose us to potential damages or other penalties. The occurrence of any of these events could have a material adverse effect on our business, financial condition, results of operations or prospects. We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights. There is substantial history of litigation and other proceedings regarding patent and intellectual property rights in the pharmaceutical industry. We may be forced to defend claims of infringement brought by our competitors and others, and ~~we~~ **51we** may institute litigation against others who we believe are infringing our intellectual property rights. The outcome of intellectual property litigation is subject to substantial uncertainties and may, for example, turn on the interpretation of claim language by the court, which may not be to our advantage, or on the testimony of experts as to technical facts upon which experts may reasonably disagree. As discussed above under the section entitled " Item ~~3~~ **1** . Business – Intellectual Property, " we received a letter dated November 30, 2022, notifying us that CIPLA submitted to the FDA an ANDA (ANDA No. 218028) for a generic version of PEDMARK ® (sodium thiosulfate solution) that contains Paragraph IV Certifications on two of our patents covering PEDMARK ®: the OHSU licensed **the US '** 190 patent, expiration date January 2038; and the **US '** 728 patent, expiration date July 2039. We received a letter dated January 5, 2023, notifying us that CIPLA submitted to the FDA a Paragraph IV Certification on the **US '** 984 patent. These patents are listed in the FDA ~~' s~~ Orange Book for PEDMARK ®. The certifications allege these patents are invalid or will not be infringed by the manufacture, use, or sale of

CIPLA' s sodium thiosulfate solution. We plan to vigorously defend our intellectual property rights related to PEDMARK ®. However, we are unable to predict the outcome of these petitions, and an invalidation of one or both of these patents may have a material adverse effect on our ability to protect our rights in PEDMARK ® beyond the market exclusivity granted from Orphan Drug Designation and PUMA. ~~50Further~~ -- **Further**, on October 29, 2021, Hope filed a petition for inter partes review (IPR2022- 00123) with the PTAB to invalidate the 190 patent, which is exclusively in- licensed from OHSU and relates to a method of using PEDMARK ®. The **US '** 190 patent was issued on March 24, 2020. On December 5, 2022, we filed a Motion to Amend the single claim of the **US '** 190 patent focusing on the treatment of medulloblastoma. On April 18, 2023, the PTAB invalidated the only claim of the **US '** 190 patent. The final written decision became effective June 20, 2023. The 190 patent was listed in the Orange Book, but in light of PTAB' s final written decision on the invalidity of the **US '** 190 patent, we requested that the FDA remove the **US '** 190 patent from the Orange Book ~~. Two U. S. patent applications claiming priority through the 190 patent remain pending at the USPTO~~ . Under our license agreements, we have the right to bring legal action against any alleged infringers of the patents we license. However, we are responsible for all costs relating to such potential litigation. We have the right to any proceeds received as a result of such litigation, but, even if we are successful in such litigation, there is no assurance we would be awarded any monetary damages. Our involvement in intellectual property litigation could result in significant expense to us. Some of our competitors have considerable resources available to them and may have a strong economic incentive to undertake substantial efforts to stop or delay us from commercializing our product. Moreover, regardless of the outcome, intellectual property litigation against or by us could significantly disrupt our development and commercialization efforts, divert our management' s attention and quickly consume our financial resources. In addition, if third parties file patent applications or issue patents claiming technology that is also claimed by us in pending applications, we may be required to participate in interference proceedings with the USPTO or in other proceedings outside the United States, including oppositions, to determine priority of invention or patentability. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel will be diverted from product development or other more productive matters. Our proprietary rights may not adequately protect our technologies and product. Our commercial success will depend in part on our ability to obtain patents and protect our existing patent position as well as our ability to maintain adequate protection of other intellectual property for our technologies, product, and any future products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The laws of some foreign countries do not protect our proprietary rights to the same extent or in the same manner as United States laws, and we may encounter significant problems in protecting and defending our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and product are covered by valid and enforceable patents or are effectively maintained as trade secrets. ~~We~~ **52We** apply for patents covering both our technologies and product, as we deem appropriate. However, we may fail to apply for patents on important technologies or product in a timely fashion, or at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. We cannot be certain that our patent applications will be approved or that any patents issued will adequately protect our intellectual property. While we are responsible for and have control over the filing and prosecuting of patent applications and maintaining patents which cover making, using or selling PEDMARK ®, we may lose any such rights if we decide to allow any licensed patent to lapse. If we fail to appropriately prosecute and maintain patent protection for PEDMARK ®, our ability to develop and commercialize PEDMARK ® may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. Moreover, the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles are evolving and remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether: ● we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications; ~~51~~ ● we or our licensors were the first to file patent applications for these inventions; ● any of the patents that cover our product will be eligible to be listed in the FDA' s compendium of " Approved Drug Products with Therapeutic Equivalence Evaluation, " sometimes referred to as the FDA ~~' s~~ Orange Book; ● others will independently develop similar or alternative technologies or duplicate any of our technologies; ● any of our or our licensors' pending patent applications will result in issued patents; ● any patents issued to us or our licensors and collaborators will provide us with any competitive advantages, or will be challenge by third parties; ● we will develop additional proprietary technologies that are patentable; ● the United States government will exercise any of its statutory rights to our intellectual property that was developed with government funding; or ● our business may infringe the patents or other proprietary rights of others. The actual protection afforded by a patent varies based on products or processes, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country, the validity and enforceability of the patents and our financial ability to enforce our patents and other intellectual property. Our ability to maintain and solidify our proprietary position for our product will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, narrowed, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. We may also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, we or any of our collaborators' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors and we may not have adequate remedies in respect of that disclosure. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive,

time consuming and uncertain. In addition, foreign courts are sometimes less willing than United States courts to protect trade secrets. 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~~ **53We** may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our product in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product in jurisdictions where we do not have any issued patents and our patent claims or other intellectual rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other ~~52aspects~~ -- **aspects** of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could 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, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Third parties may seek approval to market their own products similar to or otherwise competitive with our product. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. For example, we have received a Paragraph IV certification notice letter from CIPLA, Inc., or CIPLA, indicating that it has submitted to FDA an abbreviated new drug application, or ANDA, seeking approval to manufacture and sell a generic version PEDMARK ® (sodium thiosulfate solution) prior to the expiration of certain Orange Book- listed patents protecting PEDMARK ®. In an ANDA, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product' s listed patent or that such patent is invalid is known as a Paragraph IV certification. ~~The CIPLA ANDA contains Paragraph IV certifications with respect to two of our patents covering PEDMAR, U. S. Patent ' 190, expiration date May 2038; and ' 728, expiration date May 2039.~~ We filed a patent infringement lawsuit against CIPLA, and **will continue to** vigorously defend and enforce our intellectual property rights protecting PEDMARK ®, but we can offer no assurance that our efforts we will be successful in which case our business may be materially and adversely affected. The patent protection for our product may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue. The patents for our product have varying expiration dates and, if these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. In some of the larger potential market territories, such as the United States and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product' s development and regulatory review. For example, depending on the timing, duration and specifics of FDA marketing approval of our product, if any, one of the United States patents covering each of such approved product (s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch- Waxman Act. The Hatch- Waxman Act allows a maximum of one patent to be extended per FDA-approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, we may not be able to qualify the product or obtain the exclusive time period. If we are unable to obtain patent ~~term~~ **54term** extension / restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our United States and foreign patents. Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patent and / or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant

jurisdiction. If we fail to maintain the patents and patent applications ~~53directed~~ -- **directed** to our product, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business. We may become involved in lawsuits to protect our patents or other intellectual property rights, which could be expensive, time- consuming and ultimately unsuccessful. Competitors may infringe our patents or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, directly or through our licensors, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or of our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents or the patents we license at risk of being invalidated or interpreted narrowly and could put our or our licensors' patent applications at risk of not issuing. Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or the patents of our licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, potential infringers of our intellectual property rights may have substantially more resources than we do to defend their position, which could adversely affect the outcome of any such dispute. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Third- party claims of intellectual property infringement or misappropriation may adversely affect our business and could impede our ability to profitably commercialize our product. Our commercial success depends in part on us not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex- parte review and inter partes reexamination and post- grant review proceedings before the USPTO and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product may be subject to ~~claims~~ **55claims** of infringement of the patent rights of third parties. If a third party claims that we infringe on their products or technology, we could face a number of issues, including: ● infringement and other intellectual property claims which, with or without merit, can be expensive and time- consuming to litigate and can divert management' s attention from our core business; ● substantial damages for past infringement, which we may have to pay if a court decides that our product infringes on a competitor' s patent; ● a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which the collaborator would not be required to do; ● if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; ~~and54~~ -- **and** ● redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidate that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product could have been filed by others without the knowledge of us or our licensors. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product or the use or manufacture of our product. We may also face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party' s trade secrets, we may be prevented from further using such trade secrets, and we may be required to pay damages. If any third- party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize our product until such patent expired or unless we obtain a license. These licenses may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing our product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time- consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. In

addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us develop our product' s market fully. ~~Changes~~ **56Changes** in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our product. As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents and patent rights. Obtaining and enforcing patents and patent rights in the pharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time- consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide- ranging patent reform legislation. Further, several recent United States Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents and patent rights, once obtained. For our United States patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy- Smith America Invents Act (the " America Invents Act " or " AIA ") was signed into law. The AIA includes a number of significant changes to United States patent law, including provisions that affect the way patent applications will be prosecuted, reviewed after issuance, and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the ~~55AIA~~ **AIA** , and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of patent rights, all of which could have a material adverse effect on our business and financial condition. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a " first- inventor- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before a licensor or us could therefore be awarded a patent covering an invention of ours even if said licensor or we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patent rights depends on whether the differences between the licensor' s or our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that a licensor or we were the first to either (a) file any patent application related to our product or (b) invent any of the inventions claimed in our patents or patent applications. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all United States patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid as unpatentable even though the same evidence may be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate patent rights that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Depending on decisions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Intellectual property rights do not address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: ● Others may be able to make products that are similar to our product but that are not covered by the claims of the patents that we license from others or may license or own in the future; **57** ● Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights; ● Any of our collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own or license or will, in the future, own or license; ● Issued patents that have been licensed to us may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; ● Our competitors might conduct research and development activities in countries where we do not have license rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● Ownership of patents or patent applications licensed to us may be challenged by third parties; ● The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business. ~~56Confidentiality~~ **Confidentiality** agreements with employees, consultants and others may not adequately prevent disclosure of trade secrets and protect other proprietary information. We consider proprietary trade secrets and / or confidential know- how and unpatented know- how to be important to our business. We may rely on trade secrets and / or confidential know- how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and / or confidential know- how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets and / or confidential know- how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may

vary from jurisdiction to jurisdiction. Failure to obtain or maintain trade secrets and / or confidential know- how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and / or confidential know- how. We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent rights, that are important or necessary to the development or commercialization of our product. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms or at all, which could materially harm our business. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. ~~Further~~ **58Further** , we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on third parties to assist with research and development and to manufacture our product, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third- party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share ~~57trade~~ -- **trade** secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future, we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. Risks Related to Our IndustryDrug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Conducting clinical trials is a lengthy, time- consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we, or our potential partners, must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for their intended uses in humans. We have incurred and may continue to incur substantial expense and devote a significant amount of time to preclinical testing and clinical trials. The outcome of clinical testing is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later- stage clinical trials. In addition, regulations are not static, and regulatory agencies, including the FDA, alter their staff, interpretations and practices and may in the future impose more stringent requirements than are currently in effect, which may adversely affect our planned drug development and / or our commercialization efforts. Satisfying regulatory requirements typically takes a significant number of years and can vary substantially based on the type, complexity and novelty of the product candidate. Our business, results of operations and financial condition may be materially adversely ~~affected~~ **59affected** by any delays in, or termination of, our clinical trials. Factors that could impede our ability to generate commercially viable products through the conduct of clinical trials include: ● insufficient funds to conduct clinical trials; ● the inability to find partners, if necessary, for support, including research, development, manufacturing or clinical needs; ● the failure of clinical trials to demonstrate the safety and efficacy of our product to the extent necessary to obtain regulatory approvals; ● the failure by us or third- party investigators, CROs, or other third parties involved in the research to adhere to regulatory requirements applicable to the conduct of clinical trials; ● the failure of preclinical testing and early clinical trials to predict results of later clinical trials; ● any delay in completion of clinical trials caused by a regional disturbance where we or our collaborative partners are enrolling patients in clinical studies, such as pandemic, terrorist activities, or war, or political

unrest, a natural disaster or any other reason or event, resulting in increased costs; ~~58~~ ● any delay in obtaining advice from the FDA or similar regulatory authorities; and ● the inability to obtain regulatory approval of our product candidate following completion of clinical trials, or delays in obtaining such approvals. There can be no assurance that if our clinical trials are successfully initiated and completed, we will be able to obtain approval by regulatory authorities elsewhere in the world in a timely manner, if at all. For example, as described elsewhere, we received a CRL from the FDA in August 2020 and November 2021, regarding our NDA for PEDMARK ®, stating that it was unable to approve the application in its current form based on deficiencies identified by the FDA after completion of a pre- approval inspection of the manufacturing facility of our third- party drug product manufacturer. Although we are successful in resolving the matters raised by the FDA in the CRL, there is no guarantee we will receive regulatory approval elsewhere in the world for PEDMARK ® on a timely basis or at all. If we fail to successfully develop and commercialize PEDMARK ® outside of the United States, we may be unable to generate sufficient revenues to attain profitability, and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease. We use hazardous materials and chemicals in our research and development, and our failure to comply with laws related to hazardous materials could materially harm us. Our research and development processes, while outsourced, does involve the controlled use of hazardous materials, such as flammable organic solvents, corrosive acids and corrosive bases. Accordingly, we are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. The risk of accidental contamination or injury from these materials cannot be completely eliminated. We could be held liable for any damages that result and any such liability could exceed our resources and may not be covered by our general liability insurance. We currently do not carry insurance specifically for hazardous materials claims. We may be required to incur significant costs to comply with environmental laws and regulations, which may change from time to time. Efforts to reduce product pricing and health care reimbursement and changes to government policies could negatively affect the profitability of our product. Now that our product has achieved regulatory approval in the United States, we may be materially adversely affected by the continuing efforts of governmental and third- party payers to contain or reduce health care costs. The constraints on pricing and availability of competitive products may further limit our pricing and reimbursement policies as well as adversely impact market acceptance and commercialization of our product. ~~In~~ **60In** many markets, the pricing or profitability of healthcare products is subject to government control. In recent years, federal, state, provincial and local officials and legislators have proposed or are proposing a variety of price- based reforms to the healthcare systems in the United States, Canada and elsewhere. Some proposals include measures that would limit or eliminate payments from third- party payors to the consumer for certain medical procedures and treatments or allow government control of pharmaceutical pricing. The adoption of any such proposals or reforms could adversely affect the commercial viability of our product. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the Affordable Care Act was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U. S. pharmaceutical industry. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our product. ~~59Since~~ -- **Since** its enactment, there have been judicial and Congressional challenges to numerous aspects of the Affordable Care Act. There may also be federal and state regulatory changes that impact the Affordable Care Act or healthcare programs, insurance coverage or reimbursement generally. These efforts have increased uncertainty regarding the availability of healthcare programs, insurance coverage and reimbursement as a general matter as well as for our product, and we cannot predict how these events will impact our business. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product or additional pricing pressures. Any significant changes in the healthcare system in the United States, Canada or abroad would likely have a substantial impact on the manner in which we conduct business and could have a material adverse effect on our ability to raise capital and the viability of product commercialization. Risks Related to Owning Our Common SharesWe may be unable to maintain the listing of our common shares on the Nasdaq Capital Market or the TSX and that would make it more difficult for shareholders to dispose of our common shares. Our common shares are currently listed on the Nasdaq Capital Market and the Toronto Stock Exchange (the " TSX "). Both the Nasdaq Capital Market and the TSX have rules for continued listing, including minimum market capitalization and other requirements that we might not meet in the future. While we are exercising diligent efforts to maintain the listing of our common shares on the NASDAQ Capital Market and TSX, there can be no assurance that we will be able to do so, and our securities could be delisted. Delisting from the Nasdaq Capital Market or the TSX would make it more difficult for shareholders to dispose of our common shares and more difficult to obtain accurate quotations on our common shares. This could have an adverse effect on the price of our common shares. There can be no assurances that a market maker will make a market in our common shares on the OTCBB or any other stock quotation system after delisting. Furthermore, securities quoted over- the- counter generally have significantly less liquidity than securities traded on a national securities exchange, not only in the number of shares that can be bought and sold, but also through delays in the timing of

transactions and lower market prices than might otherwise be obtained. As a result, shareholders might find it difficult to resell shares at prices quoted in the market or at all. Furthermore, because of the limited market and generally low volume of trading in our common shares, our ~~common~~ **61common** shares are more likely to be affected by broad market fluctuations, general market conditions, fluctuations in our operating results, changes in the market' s perception of our business, and announcements made by us, our competitors or parties with whom we have business relationships. Our ability to issue additional securities for financing or other purposes, or to otherwise arrange for any financing we may need in the future, may also be materially and adversely affected by the limited market and low trading volume of our common shares. The market price of our common shares is highly volatile and could cause the value of your investment to significantly decline. Historically, the market price of our common shares has been highly volatile and the market for our common shares has from time- to- time experienced significant price and volume fluctuations, some of which are unrelated to our operating performance. From January 1, 2018 to March ~~25~~ **24** , ~~2024~~ **2025** , the closing trading price of our stock fluctuated from a high of $ 18. 45 Canadian dollars (" CAD ") per share to a low of CAD $ 4. 38 per share on the TSX. From September 13, 2017 (the date our common shares were first listed on the Nasdaq Capital Market) to March ~~25~~ **24** , ~~2024~~ **2025** , the closing trading price of our stock fluctuated from a high of $ 14. 33 per share to a low of $ 3. 30 on the Nasdaq Capital Market. Historically, our common shares have had a low trading volume, and may continue to have a low trading volume in the future. This low volume may contribute to the volatility of the market price of our common shares. It is likely that the market price of our common shares will continue to fluctuate significantly in the future. ~~60The~~ -- **The** market price of our common shares may be significantly affected by many factors, including without limitation: ● the commercialization of our sole product ~~candidate~~ , PEDMARK ®; ● the need to raise additional capital and the terms of any transaction we are able to enter into; ● other external factors generally or stock market trends in the pharmaceutical or biotechnology industries specifically; ● announcements of licensing agreements, joint ventures, collaborations or other strategic alliances that involve our product or those of our competitors; ● innovations related to our or our competitors' products; ● actual or potential clinical trial results related to our or our competitors' products; ● the status, timing and outcome of regulatory approvals; ● our financial results or those of our competitors; ● reports of securities analysts regarding us or our competitors; ● developments or disputes concerning our licensed or owned patents or those of our competitors; ● developments with respect to the efficacy or safety of our product or those of our competitors; and ● health care reforms and reimbursement policy changes nationally and internationally. Our existing principal shareholders hold a substantial number of our common shares and may be able to exercise influence in matters requiring approval of our shareholders. At March ~~25~~ **17** , ~~2024~~ **2025** , our current shareholders separately representing more than 5 % ownership of our common shares collectively represented beneficial ownership of approximately ~~47~~ **46** . ~~03~~ **24** % of our common shares. In particular, Southpoint Capital Advisors LP (" Southpoint Capital ") owns or exercises control over approximately 4. 0 million shares, representing approximately ~~15~~ **14** . **81** ~~09 % of our issued and outstanding common shares; Essetifin SpA, owns approximately 3. 2 million shares, or approximately 11. 94~~ % of our issued and outstanding common shares; Sonic Fund II, LP, owns approximately 2. 4 million shares, or approximately 8. ~~91~~ **75** % of our issued and outstanding common shares; **Essetifin SpA** ~~and Solas Capital Management~~ , owns approximately ~~1.~~ 4 **. 0** ~~million~~ **62million** shares, or approximately ~~5~~ **14** . ~~1~~ **51** % of our issued and outstanding common shares; and **Solas Capital Management, owns approximately 2. 3 million shares, or approximately 8. 18 % of our issued and outstanding common shares; and** Southpoint Capital, ~~Essetifin SpA~~ **Rosalind Advisors** , Sonic Fund II, LP, Solas Capital Management ~~,~~ and our other significant shareholders, and other insiders, acting alone or together, might be able to influence the outcomes of matters that require the approval of our shareholders, including but not limited to certain equity transactions (such as a financing), an acquisition or merger with another company, a sale of substantially all of our assets, the election and removal of directors, or amendments to our incorporating documents. These shareholders might make decisions that are adverse to your interests. The concentration of ownership could have the effect of delaying, preventing or deterring a change of control of our Company, which could adversely affect the market price of our common shares or deprive our other shareholders of an opportunity to receive a premium for our common shares as part of a sale of our Company. There are a large number of our common shares underlying outstanding options, and reserved for issuance under our stock option plan, that may be sold in the market, which could depress the market price of our shares and result in substantial dilution to the holders of our common shares. The sale or issuance of a substantial amount of our common shares in the future could cause the market price of our common shares to decline. It may also impair our ability to obtain additional financing. At March ~~25~~ **17** , ~~2024~~ **2025** , we had **0. 2 million warrants** outstanding ~~warrants~~ to purchase ~~approximately~~ **and** 0. 2 million shares of our common shares at an exercise price of $ ~~11~~ **7** . ~~00~~ **71** per common share. In addition, as of March ~~25~~ **17** , ~~2024~~ **2025** , there were approximately ~~4~~ **5** . ~~8~~ **7** million common shares issuable upon ~~61the~~ -- **the** exercise of outstanding stock options with a weighted average exercise price of $ 6. ~~27~~ **22** per common share. We may also issue further warrants as part of any future financings in addition to the additional **1.** 2 ~~. 1~~ million options to acquire our common shares currently remaining and available for future awards under our stock option plan. We may need to raise additional funds in the future to continue our operations. Any equity offering could result in significant dilution to the ownership interests of shareholders and may result in dilution of the value of such interests and any debt offering will increase financial risk. In order to satisfy our anticipated capital requirements to commercialize our product, we may need to raise additional funds through either the sale of additional equity, the issuance of securities convertible into equity, the issuance of debt, the establishment of collaborations that provide us with funding, the out- license or sale of certain aspects of our intellectual property portfolio, or from other sources. The most likely sources of financing that may be available to us in the near term are the sale of common shares and / or securities convertible or exercisable into common shares and the issuance of debt. We cannot predict the size of future issues of common shares or the future issue of securities convertible or exercisable into common shares or the effect that any such future issues and sales of common shares or other securities will have on the market price of our common shares. Any transaction involving the issue of common shares, or securities convertible or exercisable into common shares, could result in immediate and substantial dilution to present and prospective holders of our common shares.

Alternatively, we may rely on debt financing and assume debt obligations that require us to make substantial interest and capital payments and to pledge some or all of our assets as collateral to secure such debt obligations. Failure to meet out debt obligations could result in an acceleration of the debt and enforcement against our assets pledged as collateral, either of which would have an adverse effect on our operations and prospects. Our management has significant flexibility in using the current available cash. In addition to general corporate purposes (including working capital, research and development, business development and operational purposes), we currently intend to use our available cash to commercialize our product in the United States while continuing to seek regulatory approval for, and to invest in precommercial activities for PEDMARK ® outside of the United States. Depending on future developments and circumstances, we may use some of our available cash for other purposes, which may have the potential to decrease our cash runway. Notwithstanding our current intentions regarding use of our available cash, our management will have significant flexibility with respect to such use. The actual amounts and timing of expenditures will vary significantly depending on a number of factors, including the amount and timing of cash used in our operations and our research and development efforts. Management' s failure to use these funds effectively would have an adverse effect on the value of our common stock and could make it more difficult and costlier to raise funds in the future. ~~We~~ **63We** have not paid any dividends since incorporation and do not anticipate declaring any dividends in the foreseeable future. As a result, you may not be able to recoup your investment through the payment of dividends on your common shares and the lack of a dividend payable on our common shares might depress the value of your investment. For the foreseeable future, we plan to use all available funds to finance the commercialization of our product and operate our business. Our directors will determine if and when dividends should be declared and paid in the future based on our financial position at the relevant time, but since we have no present plans to pay dividends, you should not expect receipt of dividends either for your cash needs or to enhance the value of our common shares held by you. We may be a passive foreign investment company, or " PFIC, " which could result in adverse United States federal income tax consequences to U. S. investors. If we are a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U. S. Holder (as such term is defined in the section of this Annual Report entitled " Material U. S. Federal Income Tax Considerations ") of our common shares, the U. S. Holder may be subject to adverse U. S. federal income tax consequences and may be subject to additional reporting requirements. We have not made the analysis necessary to determine whether or not we are currently a PFIC or whether we have ever been a PFIC, and there can be no assurances with respect to our status as a PFIC for our current taxable year or any subsequent taxable year. If we are a PFIC for any taxable year, we intend to provide to a U. S. Holder such information as the Internal Revenue Service (" IRS ") may require, including a PFIC annual information ~~62~~ **statement, in order to enable the U. S. Holder to make and maintain a " qualified electing fund " election. For a more detailed explanation of the tax consequences of PFIC classification to U. S. Holders, see the section of this Annual Report entitled " Material U. S. Federal Income Tax Considerations. " This paragraph is qualified in its entirety by the discussion under that heading. Each U. S. shareholder should consult its own tax advisors regarding the PFIC rules and the U. S. federal income tax consequences of the acquisition, ownership, and disposition of our common shares. Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes- Oxley Act of 2002 could have an adverse effect on our business. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002 (" Section 404 ") and the rules and regulations promulgated by the SEC to implement Section 404, we are required to include in our Form 10- K a report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting. The assessment must include disclosure of any material weakness in our internal control over financial reporting identified by management. As part of the evaluation undertaken by management pursuant to Section 404, our management concluded that our internal control over financial reporting was effective as of December 31, 2024. However, if we fail to maintain an effective system of disclosure controls or internal controls over financial reporting, we may discover material weaknesses that we would then be required to disclose. Any material weaknesses identified in our internal controls could have an adverse effect on our business. We may not be able to accurately or timely report on our financial results, and we might be subject to investigation by regulatory authorities. This could result in a loss of investor confidence in the accuracy and completeness of our financial reports, which may have an adverse effect on our stock price. No evaluation process can provide complete assurance that our internal controls will detect and correct all failures within our Company to disclose material information otherwise required to be reported. The effectiveness of our controls and procedures could also be limited by simple errors or faulty judgments. In addition, if we continue to expand, through either organic growth or through acquisitions (or both), the challenges involved in implementing appropriate controls will increase and may require that we evolve some or all of our internal control processes. Under applicable SEC rules, our management' s assessment of the effectiveness of our internal control over financial reporting are not attested to by our registered public accounting firm. It is also possible that the overall scope of Section 404 may be revised in the future, thereby causing ourselves to review, revise or reevaluate our internal control processes, which may result in the expenditure of additional human and financial resources. 64Risks Related to Information TechnologyIf our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely, process proprietary, confidential, and sensitive data, including personal data (such as health- related data), intellectual property, trade secrets and any other sensitive data. Cyber- attacks, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly**

difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, which could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks, credential stuffing attacks), credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by Artificial Intelligence, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. We rely on third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation clinical trial data processing, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. 65