Risk Factors Comparison 2024-03-27 to 2023-03-09 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained elsewhere in this Annual Report on Form 10- K, including Part II, Item 7. " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and Part II, Item 8." Financial Statements," as well as our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Summary of Risk Factors Investing in our securities involves a high degree of risk. You should carefully consider all of the risks discussed in Part I, Item 1A." Risk Factors" of this Annual Report on Form 10- K, not just those discussed under this " Summary of Risk Factors " before making a decision to invest in our securities. The following is a list of some of these risks: ● We will require additional capital in order to continue our operations and may have difficulty raising additional capital. ● We rely on a collaborative outsourced business model, and disruptions with our third- party collaborators, including potential disruptions at our sole source supplier of iopofosine, AtomVie may impede our ability to gain FDA approval and delay or impair commercialization of any products. ● We cannot assure the successful development and commercialization of our compounds in development. ● Failure to complete the development of our technologies, obtain government approvals, including required FDA approvals, or comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of proposed products and result in failure to achieve revenues or maintain our ongoing business. ● The FDA has granted rare pediatric disease designation, RPDD, to iopofosine for treatment of neuroblastoma, rhabdomyosarcoma, Ewing' s sarcoma and osteosarcoma; however, we may not be able to realize any value from such designation. ● Clinical studies involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results. ● We may be required to suspend or discontinue clinical studies ~~due to~~ **because of** unexpected side effects or other safety risks that could preclude approval of our product candidates. ● Controls we or our third- party collaborators have in place to ensure compliance with all applicable laws and regulations may not be effective. ● We expect to rely on our patents as well as specialized regulatory designations such as orphan drug classification for our product candidates, but regulatory drug designations may not confer marketing exclusivity or other expected commercial benefits. ● Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidates. ● We rely on a small number of key personnel who may terminate their employment with us at any time, and our success will depend on our ability to hire additional qualified personnel. ● Acceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues. ● Regulatory approval for any approved product is limited by the FDA, the European Commission and other regulators to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may incur significant liability if it is determined that we are promoting the " off- label " use of any of our future product candidates if approved. ● Any product for which we have obtained regulatory approval, or for which we obtain approval in the future, is subject to, or will be subject to, extensive ongoing regulatory requirements by the FDA, EMA and other comparable regulatory authorities, and if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, we may be subject to penalties, we may be unable to generate revenue from the sale of such products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased. ● The COVID- 19 pandemic as well as conflicts, military actions, terrorist attacks, natural disasters. public health crises, cyber- attacks and general instability could materially adversely affect our business. ● Failure to meet Nasdaq' s continued listing requirements could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital. ● Our stock price has experienced price fluctuations. Risks Related to Capital and Our OperationsWe will require additional capital in order to continue our operations and may have difficulty raising additional capital. We expect that we will continue to generate operating losses for the foreseeable future. As of December 31, ~~2022~~ **2023** , our consolidated cash balance was approximately $ ~~19.~~9 **. 6** million. We believe our cash balance as of December 31, ~~2022~~ **2023** , **in combination with the funds generated by the warrants exercised by investors in January 2024 (see Note 13 to our audited financial statements in Item 8 of this 10- K)** is adequate to fund our basic budgeted operations into the fourth quarter of ~~2023~~ **2024** . ~~31After~~ **During** the third quarter ended **September 30** , ~~in October 2022~~ **2023** , the Company completed a ~~registered direct offering and concurrent~~ private placement **with certain institutional investors expected to result in gross proceeds** of ~~shares~~ **up to $ 102. 9 million, including gross proceeds** of **$ 24. 5 million which the Company received at closing. In January 2024,** the Company' s **Tranche A** ~~common stock, prefunded~~ warrants **were all exercised resulting** ~~and common warrants. The offering and private placements resulted~~ in ~~total~~ gross proceeds of ~~approximately~~ $ ~~10~~ **44** . ~~7~~ **1** million with net proceeds ~~to the Company~~ of approximately $ ~~9~~ **42** . ~~7~~ **8** million after deducting estimated offering expenses (see Note ~~8~~ **13** to our audited financial statements). The Company' s ability to execute its current operating plan depends on its ability to obtain additional funding via the sale of equity and / or debt securities, a strategic transaction or other source of capital. The Company plans to continue actively pursuing financing alternatives, however, there can be no assurance that it will obtain the necessary funding, raising substantial doubt ~~about~~ **31about** the Company' s ability to continue as a going concern within one year of the date these financial statements are issued.

The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our capital requirements and our ability to meet them depend on many factors, including: ● the number of potential products and technologies in development; ● continued progress and cost of our research and development programs; ● progress with preclinical studies and clinical studies; ● the time and costs involved in obtaining regulatory clearance; ● costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims; ● costs of developing sales, marketing and distribution channels and our ability to sell our drugs; ● costs involved in establishing manufacturing capabilities for clinical study and commercial quantities of our drugs; ● competing technological and market developments; ● claims or enforcement actions with respect to our products or operations; ● market acceptance of our products; ● costs for recruiting and retaining management, employees and consultants; ● our ability to manage computer system failures or security breaches; ● costs for educating physicians regarding the application and use of our products; ● whether we are able to maintain our listing on a national exchange; ● uncertainty and economic instability resulting from conflicts, military actions, terrorist attacks, natural disasters, public health crises, including the occurrence of a contagious disease or illness, such as the COVID- 19 coronavirus, cyber-attacks and general instability; and ● the condition of capital markets and the economy generally, both in the U. S. and globally. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than expected. We may seek to raise any additional funds through the issuance of any combination of common stock, preferred stock, warrants and debt financings or by executing collaborative arrangements with corporate partners or other sources, any of which may be dilutive to existing stockholders or have a material effect on our current or future business prospects. If we cannot secure adequate financing when needed, we may be required to delay, scale back or eliminate one or more of our research and development programs or to enter into license or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves. In the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and / or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves. In such an event, our business, prospects, financial condition and results of operations may be adversely affected. 32The COVID- 19 pandemic could materially and adversely affect our business. The COVID- 19 pandemic could significantly disrupt our business and may prevent us from conducting business activities ~~due to~~ **because of** spread of the disease, or ~~due to~~ **as a result of** shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions have included restrictions on our ability to travel, as well as temporary closures. While we have not yet experienced any significant impacts as a result of the pandemic **other than delays in clinical trial enrollment** , it is not possible at this time to estimate the ultimate impact that it could have on our business. The continued impacts of COVID- 19 including new virus strains and the measures taken by government authorities ~~has~~ **have** created uncertainties and could delay our ongoing clinical studies or the manufacture or shipment of iopofosine for clinical studies ~~. We continue to evaluate the impact COVID- 19 may have on our ability to effectively conduct our business. Our clinical trial sites may be affected by travel or quarantine restrictions imposed by federal, state or local governments. We may in the future need to update or suspend our clinical studies as a result of the pandemic. In addition, we have made and we (and our CROs) may need to make certain adjustments to the operation of clinical studies in an effort to ensure the monitoring and safety of patients and minimize risks to trial data integrity during the pandemic in accordance with the guidance issued by the FDA in 2020, which describes a number of considerations for sponsors of clinical studies impacted by the pandemic, including, among other requirements, the requirements to include in the clinical trial report contingency measures implemented to manage the clinical trial, any disruption of the clinical trial as a result of the COVID- 19 pandemic, and analyses and corresponding discussions that address the impact of implemented contingency measures on the safety and efficacy results reported for the clinical trial. To the extent we (or our third- party suppliers and manufacturers) are required to implement additional or to modify existing policies and procedures for our clinical studies and / or manufacturing functions, or if the pandemic significantly impacts recruitment of patients or the conduct of our clinical studies, our anticipated timelines for initiating or completing clinical studies and seeking regulatory approval may be substantially delayed, and we may incur additional costs. We cannot currently fully forecast the scope of impact that the COVID- 19 pandemic may have overall on clinical study results, including the timing thereof, or our ability to continue to treat patients enrolled in our trials, enroll and assess new patients, supply study drug and obtain complete data points in accordance with study protocol. Also, to the extent FDA and other regulatory authorities experience any delays or limited resources in reviewing our regulatory applications or requests for meetings and / or guidance, and inspection of manufacturing facilities prior to regulatory approval due to the COVID- 19 pandemic or other reasons, we may experience significant delays in our anticipated timelines for our clinical studies and / or seeking regulatory approvals, which could adversely affect our business. Due to the ongoing COVID- 19 pandemic, it is also possible that we could experience delays in the timing of our interactions with regulatory authorities due to absenteeism by governmental employees or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID- 19, which could delay or limit our ability to make planned regulatory submissions or develop and commercialize our product candidates on anticipated timelines. Health regulatory agencies globally may experience prolonged disruptions in their operations as a result of the COVID- 19 pandemic. For example, in response to the COVID- 19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products inspections of domestic manufacturing facilities through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. On July 10, 2020, the FDA announced that it is working toward the goal of restarting on- site inspections it deems to be " mission critical. " On August 19, 2020, the FDA published guidance clarifying how it intends to conduct inspections during the COVID- 19 pandemic, including how it plans to determine which inspections are " mission critical. " The Agency published an updated form of this guidance on May 17, 2021. Additionally, on April 14, 2021, the FDA issued a guidance document in which the~~

~~FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in- person inspection would not be prioritized, deemed mission- critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. It is unclear how the FDA' s policies and guidance will impact any inspections of our facilities, including our clinical trial sites. The FDA has since adjusted its inspection activities in response to the ongoing COVID- 19 pandemic. On December 29, 2021, the Agency implemented temporary changes to its inspectional activities to ensure the safety of its employees and regulated firms. On February 2, 2022, FDA announced that it would resume domestic surveillance inspections across all product areas on February 7, 2022. We cannot predict whether, and when, the FDA will decide to pause or resume inspections due to the COVID- 19 pandemic. Regulatory authorities outside the US may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic. It is unknown how long these disruptions could continue. Any de- prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the completion of our clinical trials. 33Although we expect no material impact on the supply of iopofosine for our current clinical studies, should our third- party manufacturers experience extended disruptions, we could experience delays in future trials. Further, in June 2020, the FDA issued a guidance on good manufacturing practice considerations for responding to COVID- 19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs. Such guidance and any future guidance or regulatory requirements impacting drug product manufacturing, including delays associated with complying with new requirements, could impact the operations of our contract manufacturers, our business, and our ability to obtain sufficient supplies for our clinical development on a timely basis. The COVID- 19 pandemic continues to rapidly evolve. While the extent of the impact of the COVID- 19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis could have a material negative impact on our business, financial condition and operating results. To the extent that COVID- 19 pandemic impacts our business in any way, it may also have the effect of heightening the impact of other risk factors disclosed herein~~ . Conflicts, military actions, terrorist attacks, natural disasters. public health crises, including the occurrence of a contagious disease or illness, such as the COVID- 19 coronavirus, cyber- attacks and general instability could adversely affect our business. Conflicts, military actions, terrorist attacks, natural disasters, public health crises and cyber- attacks have precipitated economic instability and turmoil in financial markets. Instability and turmoil may result in raw material cost increases. In addition, the long- term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our businesses. The uncertainty and economic disruption resulting from hostilities, military action, acts of terrorism, natural disasters, public health crises or cyber- attacks may impact our operations or those of our suppliers. Accordingly, any conflict, military action, terrorist attack, natural disasters, public health crises or cyber- attack that impacts us or any of our suppliers, could have a material adverse effect on our business, liquidity, prospects, financial condition and results of operations. War, terrorism, other acts of violence, or natural or manmade disasters may affect the markets in which we operate, our patients and resources required in our research and development activities. Our business may be adversely affected by political instability, disruption or destruction in a geographic region in which we operate, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest, and natural or manmade disasters, including famine, flood, fire, earthquake, storm or pandemic events and spread of disease, such as the COVID- 19 pandemic and the significant military action against Ukraine by Russia. Such events may affect our business by increasing prices for resources required in our research and development activities or limiting our access to patients for our clinical trials which may delay our progress on one or more of our clinical or preclinical drug product candidates. Our business and operations may be materially adversely affected in the event of computer system failures or security breaches. Despite the implementation of security measures, our internal computer systems, and those of our third- party manufacturers, contract research organizations and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber- attacks, phishing attempts, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption in our business. For example, the loss of clinical study data from ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets, inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, lack of access to our clinical data, or disruption of the manufacturing process, we could incur liability and the further development of our drug candidates could be delayed. We may also be vulnerable to cyber- attacks or other malfeasance by hackers. This type of breach of our cybersecurity may compromise our confidential and financial information, adversely affect our business, or result in legal proceedings. Further, these cybersecurity breaches may inflict reputational harm upon us that may result in decreased market value and erode public trust. ~~34Failure~~ -- **Failure** to meet investor and stakeholder expectations regarding environmental, social and corporate governance, or " ESG " matters may damage our reputation. There is an increasing focus from certain investors, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow. If our ESG practices fail to meet ~~investor~~ **33investor** , employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, Board of Directors and employee diversity, human capital management, corporate governance and transparency, our reputation, brand, appeal to investors and employee retention may be negatively impacted, which could have a material adverse effect on our business or financial condition. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. Our ability to utilize our federal net operating loss and tax credit carryforwards may be limited

under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code). The limitations apply if we experience an " ownership change ", generally defined as a greater than 50 percentage point change in the ownership of our equity by certain stockholders over a rolling three- year period. Similar provisions of state tax law may also apply. We have not evaluated whether such an ownership change has occurred previously. If we have experienced an ownership change at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change and, consequently, the limitations under Sections 382 and 383 of the Code. As a result, if or when we earn net taxable income, our ability to use our net operating loss carryforwards and other tax attributes to offset such taxable income may be subject to limitations, which could adversely affect our future cash flows. Risks Related to Manufacturing and SupplyWe rely on a collaborative outsourced business model, and disruptions with our third- party collaborators, including potential disruptions at our sole source supplier of iopofosine, AtomVie, may impede our ability to gain FDA approval and delay or impair commercialization of any products. We are in the preclinical and clinical study phases of product development and commercialization. We have closed manufacturing operations located at our former corporate headquarters in Wisconsin and have implemented a collaboration outsourcing model to more efficiently manage costs. We rely significantly on contracts with third parties to use their facilities to conduct our research, development and manufacturing. We have engaged ~~CPDC~~ **AtomVie** , which has been a validated cGMP manufacturing organization specializing in radiopharmaceuticals, as our exclusive source to supply drug product for our ongoing research and clinical studies, including our Phase 1 and Phase 2 studies of iopofosine. In addition, we rely exclusively on contract research organizations to conduct research and development. Any inability of these organizations to fulfill the requirements of their agreements with us may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technology and products. Our reliance on third- party collaborators exposes us to risks related to not being able to directly oversee the activities of these parties. Furthermore, these collaborators, whether foreign or domestic, may experience regulatory compliance difficulties, mechanical shutdowns, employee strikes, or other unforeseeable acts that may delay fulfillment of their agreements with us. This may lead to the stopping or delay of our clinical trials or commercial manufacturing activity. For example, in 2018, our CMO, ~~CPDC~~ **AtomVie** , was placed on import alert following an FDA inspection, which resulted in our studies being placed on a clinical hold, until we received an FDA exception allowing us to import our study drug for use in clinical trials. The import alert on ~~CPDC~~ **AtomVie** was removed in 2019. Failure of any of these collaborators to provide the required services in a timely manner or on commercially reasonable terms could materially delay the development and approval of our products, increase our expenses, and materially harm our business, prospects, financial condition and results of operations. ~~35Our~~ -- **Our** current and anticipated future dependence upon these third- party manufacturers may adversely affect our ability to develop and commercialize product candidates on a timely and competitive basis, which could have an adverse effect on sales, results of operations and financial condition. If we were required to transfer manufacturing processes to other third- party manufacturers and we were able to identify an alternative manufacturer, we would still need to satisfy various regulatory requirements. Satisfaction of these requirements could cause us to experience significant delays in receiving an adequate supply of our products and products in development and could be costly. Moreover, we may not be able to transfer processes that are proprietary to the manufacturer, if any. These manufacturers may not be able to produce material on a timely basis or manufacture material at the quality level or in the quantity required to meet our development timelines and applicable regulatory requirements and may also experience a shortage in qualified personnel, including ~~due to~~ **as a result of** the impacts of the COVID- 19 pandemic. We may not be able to maintain or renew our existing third- party manufacturing arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third- party ~~manufacturers~~ **34manufacturers** could terminate or decline to renew our manufacturing arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on acceptable terms, our planned clinical trials may be significantly delayed. Manufacturing delays could postpone the filing of our IND applications and / or the initiation or completion of clinical trials that we have currently planned or may plan in the future. Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, the EMA, national competent authorities in the EU and UK and other federal and state government and regulatory agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers' compliance with these regulations and standards and they may not be able to comply. Switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all. Additionally, if we are required to enter into new supply arrangements, we may not be able to obtain approval from the FDA of any alternate supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of any related product candidates. Failure of our third- party manufacturers or us to comply with applicable regulations, whether ~~due to~~ **because of** the impacts of the ~~ongoing~~ COVID- 19 pandemic or otherwise, could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of our product candidates, injunctions, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, warning or similar letters or civil, criminal or administrative sanctions against the company, any of which could adversely affect our business. We believe that we have a good working relationship with our third- party collaborators. However, should the situation change, we may be required to relocate these activities on short notice, and we do not currently have access to alternate facilities to which we could relocate our research, development and / or manufacturing activities. The cost and time to establish or locate an alternate research, development and / or manufacturing facility to develop our technology would be substantial and would delay obtaining FDA approval and commercializing our products. Furthermore, if our products are approved for commercial sale, we will need to work with our existing third- party collaborators to ensure sufficient capacity, or

engage additional parties with the capacity, to commercially manufacture our products in accordance with FDA and other regulatory requirements. There can be no assurance that we would be able to successfully establish any such capacity or identify suitable manufacturing partners on acceptable terms. Risks Related to Research and Development and the FDAWe cannot assure the successful development and commercialization of our compounds in development. At present, our success is dependent on one or more of the following to occur: the successful development of iopofosine for the treatment of a hematologic or solid tumor cancer including Waldenstrom' s macroglobulinemia, multiple myeloma and B- Cell lymphomas or the treatment of pediatric solid tumors and lymphomas; the development of new PDCs, specifically new products developed from our PDC program, and the advancement of our PDC agents through research and development; and / or commercialization partnerships. ~~36We~~ **We** are a late- stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer. We leverage our PDC platform to specifically target ~~treatments to~~ cancer cells. The PDC platform possesses the potential for the discovery and development of the next generation of cancer- targeting agents. The PDC platform features include the capacity to link with almost any molecule, the delivery of a significant increase in targeted oncologic payload, and the ability to target all tumor cells. As a result, we believe that we can generate PDCs to treat a broad range of cancers with the potential to improve the therapeutic index of oncologic drug payloads, enhance or maintain efficacy while reducing adverse events by minimizing drug delivery to healthy cells, and increase delivery to cancerous cells and cancer stem cells. Our proposed products and their potential applications are in clinical and manufacturing / process development and face a variety of risks and uncertainties inherent in the development of pharmaceutical products, including the following: ● The inherent difficulty in selecting the right drug and drug target and avoiding unwanted side effects, as well as unanticipated problems relating to product development, testing, enrollment, obtaining regulatory approvals, maintaining regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates; **35** ● Future clinical study results may show that our cancer- targeting and delivery technologies are not well- tolerated by patients at their effective doses or are not efficacious. In future clinical trials, we or our partners may discover additional side effects and / or a higher frequency of side effects than those observed in previously completed clinical trials. ● Future clinical study results may be inconsistent with testing results obtained to- date. The results of preliminary and mid- stage clinical trials do not necessarily predict clinical or commercial success, and larger later- stage clinical trials may fail to confirm the results observed in the previous clinical trials. ● A clinical trial may show that a product candidate is safe and effective for certain patient populations in a particular indication, but other clinical trials may fail to confirm those results in a subset of that population or in a different patient population, which may limit the potential market for that product candidate. ● Even if our cancer- targeting and delivery technologies are shown to be safe and effective for their intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities at reasonable prices or at all. ● Our ability to complete the development and commercialization of our cancer- targeting and delivery technologies for their intended use is substantially dependent upon our ability to raise sufficient capital or to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, our products. ● Even if our cancer- targeting and delivery technologies are successfully developed, approved by all necessary regulatory authorities, and commercially produced, there is no guarantee that there will be market acceptance of our products. ● Our competitors may develop therapeutics or other treatments that are superior or less costly than our own with the result that our product candidates, even if they are successfully developed, manufactured and approved, may not generate sufficient revenues to offset the development and manufacturing costs of our product candidates. If we are unsuccessful in dealing with any of these risks, or if we are unable to successfully advance the development of our cancer- targeting and delivery technologies for some other reason, our business, prospects, financial condition and results of operations may be adversely affected. With respect to our own compounds in development, we have established anticipated timelines with respect to the initiation of clinical trials based on existing knowledge of the compounds. However, we cannot provide assurance that we will meet any of these timelines for clinical development. Additionally, the initial results of a completed earlier clinical trial of a product candidate do not necessarily predict final results and the results may not be repeated in later clinical trials. Because of the uncertainty of whether the accumulated preclinical evidence (PK, pharmacodynamic, safety and / or other factors) or early clinical results will be observed in later clinical trials, we can make no assurances regarding the likely results from our future clinical trials or the impact of those results on our business. ~~37Failure~~ -- **Failure** to complete the development of our technologies, obtain government approvals, including required FDA approvals, or comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of proposed products and result in failure to achieve revenues or maintain our ongoing business. Our research and development activities and the manufacture and marketing of our intended products are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the U. S. and abroad. Before receiving approval to market our proposed products by the FDA, we will have to demonstrate that our products are safe and effective for the patient population for the diseases that are to be treated. Clinical studies, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug, and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacturing, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, clinical studies and regulatory approval can take many years to accomplish and require the expenditure of substantial financial, managerial and other resources. We cannot predict whether regulatory clearance or approval will be obtained for any product that we hope to develop. Of particular significance to us are the requirements relating to research and development and testing. The activities associated with the ~~research~~ **36research**, development and commercialization of iopofosine and other future candidates in our pipeline must undergo extensive clinical trials, which can take many years and require substantial expenditures, subject to extensive regulation by the FDA and other regulatory agencies in the U. S. and by comparable authorities in other countries. The process of obtaining regulatory approvals in the U. S. and other foreign jurisdictions is expensive, and lengthy, if approval is obtained at

all. Before commencing clinical trials in humans, we, or our collaborative partners, will need to submit and receive approval from the FDA of an IND application. Clinical trials are subject to oversight by institutional review boards and the FDA and: ● must be conducted in conformance with the FDA' s good clinical practices and other applicable regulations; ● must meet requirements for institutional review board oversight; ● must meet requirements for informed consent; ● are subject to continuing FDA and regulatory oversight; ● may require large numbers of test subjects; and ● may be suspended by us, our collaborators or the FDA at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in the IND or the conduct of these trials. We do not know whether we will be permitted to undertake clinical trials of potential products beyond the trials already concluded and the trials currently in process. It will take us or our collaborative partners several years to complete any such testing, and failure can occur at any stage of testing. Interim results of trials do not necessarily predict final results, and acceptable results in early trials may not be repeated in later trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. Before receiving FDA approval or similar approval in the European Union or other jurisdiction to market a product, we must demonstrate with substantial clinical evidence that the product is safe and effective in the patient population and the indication that will be treated. Data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approvals. Our clinical trials may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. In connection with clinical trials of our product candidates, we may face the following risks among others: ● the product candidate may not prove to be effective; ● the product candidate may cause harmful side effects; ● the clinical results may not replicate the results of earlier, smaller trials; ~~38~~ ● we or third parties with whom we collaborate, may be significantly impacted by the evolving impacts of the ongoing COVID- 19 pandemic; ● we, or the FDA or similar foreign regulatory authorities, may delay, terminate or suspend the trials; ● our results may not be statistically significant; ● patient recruitment and enrollment may be slower than expected; ● patients may drop out of the trials or otherwise not enroll; and ● regulatory and clinical trial requirements, interpretations or guidance may change. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA and decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Varying interpretations of the data obtained ~~from~~ **37from** preclinical and clinical testing could delay, limit or prevent regulatory approval of our products for any individual, additional indications. **To** ~~In order to~~ be commercially viable, we must successfully research, develop, manufacture, introduce, obtain the required regulatory approval described above for, our product candidates, in order to market and distribute our product candidates. This includes meeting a number of critical developmental milestones, including: ● demonstrating benefit from delivery of each specific drug for specific medical indications; ● demonstrating through preclinical and clinical studies that each drug is safe and effective; and ● demonstrating that we have established viable FDA cGMPs capable of potential scale- up. The timeframe necessary to achieve these developmental milestones may be long and uncertain, and we may not successfully complete these milestones for any of our intended products in development. In addition to the risks previously discussed, our technology is subject to developmental risks that include the following: ● uncertainties arising from the rapidly growing scientific aspects of drug therapies and potential treatments; ● uncertainties arising as a result of the broad array of alternative potential treatments related to cancer and other diseases; and ● expense and time associated with the development and regulatory approval of treatments for cancer and other diseases. In addition, delays or rejections may be encountered based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, adverse publicity, as well as other regulatory action against our potential products or us. **To** ~~In order to~~ conduct the clinical studies that are necessary to obtain approval by the FDA to market a product, it is necessary to receive clearance from the FDA to conduct such clinical studies. The FDA can halt clinical studies at any time for safety reasons or because we or our clinical investigators do not follow the FDA' s requirements for conducting clinical studies. If any of our studies are halted, we will not be able to obtain FDA approval until and unless we can address the FDA' s concerns. If we are unable to receive clearance to conduct clinical studies for a product, we will not be able to achieve any revenue from that product in the U. S., as it is illegal to sell any drug for use in humans in the U. S. without FDA approval. If regulatory approval of a product is granted, this approval will be limited to those indications or disease states and conditions for which the product is demonstrated through clinical trials to be safe and efficacious. We cannot assure you that any compound developed by us, alone or with others, will prove to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing approval. ~~39Even~~ -- **Even** if we do ultimately receive FDA approval for any of our products, these products will be subject to extensive ongoing regulation, including regulations governing manufacturing, labeling, packaging, testing, dispensing, prescription and procurement quotas, record keeping, reporting, handling, shipment and disposal of any such drug. Failure to obtain and maintain required registrations or to comply with any applicable regulations could further delay or preclude development and commercialization of our drugs and subject us to enforcement action. Outside the US, our ability, or that of our collaborative partners, to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks and costs associated with FDA approval described above and may also include additional risks and costs, such as the risk that such foreign regulatory authorities, which often have different regulatory and clinical trial requirements, interpretations and guidance from the FDA, may require additional clinical trials or results for approval of a product candidate, any of which could result in delays, significant additional costs or failure to obtain such regulatory approval. There can be no assurance, however, that we or our collaborative partners will not have to provide additional information or analysis, or conduct additional clinical trials, before

receiving approval to market product candidates. ~~The~~ **38The** FDA has granted rare pediatric disease designation, RPDD, to iopofosine for treatment of neuroblastoma, rhabdomyosarcoma, Ewing' s sarcoma and osteosarcoma; however, we may not be able to realize any value from such designation. ~~Our iopofosine~~ **Iopofosine** ~~compound~~ has received RPDD designation from the FDA for the treatment of neuroblastoma, rhabdomyosarcoma, osteosarcoma and Ewing' s sarcoma. The FDA defines a " rare pediatric disease " as a disease that affects fewer than 200, 000 individuals in the U. S. primarily under the age of 18 years old, or a patient population greater than 200, 000 in the U. S. when there is no reasonable expectation that the cost of developing and making available the drug in the U. S. will be recovered from sales in the U. S. for that drug or biological product. Under the FDA' s Rare Pediatric Disease Priority Review Voucher Program, upon the approval of an NDA or a BLA for the treatment of a rare pediatric disease, the sponsor of such application could be eligible for a Rare Pediatric Disease Priority Review Voucher that can be redeemed to obtain priority review for a subsequent NDA or BLA. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U. S. within one year following the date of approval. In addition, the priority review voucher is only awarded to an NCE. Thus, if iopofosine is approved first for an indication that is not a rare pediatric disease, our application may not be eligible to receive the voucher. There is no assurance we will receive a Rare Pediatric Disease Priority Review Voucher or that it will result in a faster development process, review or approval for a subsequent marketing application. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we were to sell a Priority Review Voucher. In December 2020, the Priority Review Voucher Program was extended by the FDA permitting additional grants through September 2026 for rare pediatric diseases. It is possible that even if we obtain approval for iopofosine and qualify for a priority review voucher, the program may no longer be in effect at the time of such approval. Clinical studies involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results. **To** ~~In order to~~ obtain regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical studies to demonstrate safety and efficacy of these product candidates. Clinical testing is expensive, it can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical study process. ~~40We~~ **We** may experience delays in clinical testing of our product candidates. We do not know whether planned clinical studies will begin on time, need to be redesigned, or be completed on schedule, if at all. Clinical studies can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, reaching agreement on acceptable clinical study terms with prospective sites, obtaining institutional review board approval to conduct a study at a prospective site, recruiting patients to participate in a study, or obtaining sufficient supplies of clinical study materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, competing clinical studies, and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles or other drugs undergoing development in clinical studies. Any delays in completing our clinical studies will increase our costs, slow down our product development and approval process, and delay our ability to generate revenue. **Additionally** ~~In addition~~ , the results of preclinical studies and early clinical studies of our product candidates do not necessarily predict the results of later- stage clinical studies. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical studies of our product candidates may not be sufficient to support the submission of an NDA or to obtain regulatory approval in the U. S. or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or will achieve sales or profits. **Furthermore** ~~In addition~~ , we typically rely on third- party clinical investigators to conduct our clinical trials and other third- party organizations to oversee the operations of such trials and to perform data collection and analysis. The clinical investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. Failure of the third- party organizations to meet their obligations, whether ~~due to~~ **because of** the impacts of the ongoing COVID- 19 pandemic or otherwise, could adversely affect clinical development of our products. As a result, we may face additional delaying factors outside our control if these parties do not ~~perform~~ **39perform** their obligations in a timely fashion. For example, any number of those issues could arise with our clinical trials causing a delay. Delays of this sort could occur for the reasons identified above or other reasons. If we have delays in conducting the clinical trials or obtaining regulatory approvals, our product development costs will increase. For example, we may need to make additional payments to third- party investigators and organizations to retain their services or we may need to pay recruitment incentives. If the delays are significant, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to become profitable will be delayed. Moreover, these third- party investigators and organizations may also have relationships with other commercial entities, some of which may compete with us. If these third- party investigators and organizations assist our competitors at our expense, it could harm our competitive position. Our clinical studies may not demonstrate sufficient levels of efficacy necessary to obtain the requisite regulatory approvals for our drugs, and our proposed drugs may not be approved for marketing. We may not be able to initiate or continue clinical studies or trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials as required by the FDA or other regulatory authorities, whether ~~due to~~ **a result of** the impacts of the ongoing COVID- 19 pandemic or otherwise. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our clinical trials may be delayed, or our clinical trials could become too expensive to complete. Significant delays in clinical testing could negatively impact our product development costs and timing. Our estimates regarding timing are based on a number of assumptions,

including assumptions based on past experience with our other clinical programs. If we are unable to enroll the patients in these trials at the projected rate, the completion of the clinical program could be delayed and the costs of conducting the program could increase, either of which could harm our business. **We** ~~Due to the evolving effects of the COVID- 19 pandemic, for several of our development programs, we are experiencing a disruption or delay in our ability to enroll and assess patients, maintain patient enrollment, supply study drug, report trial results, or interact with regulators, ethics committees or other important agencies due to limitations in employee resources or otherwise. In addition, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID- 19 may adversely impact our clinical trial operations. In light of the evolving effects of the COVID- 19 pandemic, we have taken, and will continue to take, measures to implement remote and virtual approaches to clinical development, including remote patient monitoring where possible, and if the COVID- 19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects. 41We~~ may be required to suspend or discontinue clinical studies ~~due to~~ **because of** unexpected side effects or other safety risks that could preclude approval of our product candidates. Our clinical studies may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical studies if at any time we believe that they present an unacceptable risk to the clinical study patients. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical studies at any time if they believe that the clinical studies are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical study patients. Administering any product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical studies of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical studies. ~~Risks~~ **40Risks** Related to Legal Compliance and LitigationControls we or our third- party collaborators have in place to ensure compliance with all applicable laws and regulations may not be effective. We and our third- party collaborators are subject to federal, state and local laws and regulations governing the storage, use and disposal of hazardous materials and waste products. Current or future regulations may impair our research, development, manufacturing and commercialization efforts. The inability of our third- party collaborators to maintain the required licenses and permits for any reason will negatively impact our manufacturing, **and** research and development activities. In addition, we may be required to indemnify third- party collaborators against certain liabilities arising out of any failure by them to comply with such regulations and / or laws. If we or our third **-** party collaborators fail to comply with any of these regulations and / or laws, a range of consequences could result, including the suspension or termination of clinical studies, failure to obtain approval of a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, or other sanctions or litigation. We are exposed to product, clinical and preclinical liability risks that could create a substantial financial burden should we be sued. Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. In addition, the use in our clinical studies of pharmaceutical products that we, or our current or potential collaborators, may develop and then subsequently sell, may cause us to bear a portion of, or all, product liability risks. While we carry an insurance policy covering up to $ 5, 000, 000 per occurrence and $ 5, 000, 000 in the aggregate for liability incurred in connection with such claims should they arise, there can be no assurance that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance if required, will be available or, if available, will be available on commercially reasonable terms. Furthermore, our current and potential partners with whom we have collaborative agreements, or our future licensees, may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have a net worth sufficient to satisfy any product liability claims. A successful product liability claim or series of claims brought against us could have a material adverse effect on our business, prospects, financial condition and results of operations. Risks Related to Intellectual PropertyWe expect to rely on our patents as well as specialized regulatory designations such as orphan drug classification for our product candidates, but regulatory drug designations may not confer marketing exclusivity or other expected commercial benefits. We expect to file for ODD or other regulatory designations (fast track, break- through, priority review, etc.) as appropriate for our product candidates. We have been granted ODD in the U. S. for iopofosine as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma, Ewing' s sarcoma and lymphoplasmacytic lymphoma / Waldenstrom' s macroglobulinemia. Additionally, we have been granted ODD in Europe for iopofosine as a therapeutic for the treatment of multiple myeloma and Waldenstrom' s macroglobulinemia. ~~42Under~~ -- **Under** the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200, 000 in the US, or a patient population greater than 200, 000 in the US where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the US. In the US, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. Even though we have received **ODD** ~~orphan drug designation~~ as described above, we may not be the first to obtain marketing approval for the orphan- designated indication ~~due to~~ **because of** the uncertainties

associated with developing pharmaceutical products. For any product candidate for which we have been or will be granted ODD in a particular indication, it is possible that another company also holding ODD for the ~~same~~ **41same** product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company' s period of exclusivity expires. In addition, exclusive marketing rights in the US for iopofosine for an orphan- designated indication or any future product candidate may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. We will not be able to rely on it to exclude other companies from manufacturing or selling products using the same principal molecular structural features for the same indication beyond these timeframes without our patent portfolio. Even if we were the first to obtain marketing authorization for an orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during the seven- year period of marketing exclusivity, such as if the later product is shown to be clinically superior to the product with orphan exclusivity. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. In addition, exclusive marketing rights in the US for iopofosine or any future product candidate may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Further, the seven- year marketing exclusivity, if granted, would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted ODD, or for other indications if not for our patent portfolio, or for the use of other types of products in the same indications as our orphan product. Furthermore, although the ODD and exclusivity are in effect right now, the FDA has the authority to modify this assessment at any time. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a recent decision by the U. S. Court of Appeals for the Eleventh Circuit. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, results of operations, financial condition and prospects. Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidates. If a product candidate is intended for the treatment of a serious or life- threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA fast track designation. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development, and the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. ~~43However~~ -- **However** , fast track designation does not change the standards for approval and does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while the FDA has granted fast track designation to iopofosine for WM patients having received two or more prior treatment regimens and / or we may seek and receive fast track designation for our future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA' s priority review procedures. We may face litigation from third parties claiming our products infringe on their intellectual property rights, particularly because there is often substantial uncertainty about the validity and breadth of medical patents. We may be exposed to future litigation by third parties based on claims that our technologies, products or activities infringe on the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents, and the breadth and scope of trade- secret protection, involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us, ~~whether~~ **42whether** valid or not, could result in substantial costs, place a significant strain on our financial and managerial resources, and harm our reputation. License agreements that we may enter into in the future would likely require that we pay the costs associated with defending this type of litigation. In addition, intellectual property litigation or claims could force us to do one or more of the following: ● cease selling, incorporating or using any of our technologies and / or products that incorporate the challenged intellectual property, which would adversely affect our ability to generate revenue; ● obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or ● redesign our products, which would be costly and time- consuming. If we are unable to adequately protect or enforce our rights to intellectual property or to secure rights to third- party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to protect our intellectual property rights. Our ability to obtain licenses to patents, maintain trade- secret protection, and operate without infringing the proprietary rights of others will be important to commercializing any products under development. Therefore, any disruption in access to the technology could substantially delay the development of our technology. The patent positions of biotechnology and pharmaceutical companies, such as ours, for products that involve licensing agreements are frequently uncertain and involve complex legal and factual questions. In addition, the coverage

claimed in a patent application can be significantly reduced before the patent is issued or in subsequent legal proceedings. Consequently, our patent applications and any issued and licensed patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. To the extent we license patents from third parties, the early termination of any such license agreement would result in the loss of our rights to use the covered patents, which could severely delay, inhibit or eliminate our ability to develop and commercialize compounds based on the licensed patents. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued or licensed to us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U. S. law. We also rely on trade secrets, technical know- how and continuing technological innovation to develop and maintain our competitive position. Although we generally require our employees, consultants, advisors **,** and collaborators to execute appropriate confidentiality and assignment- of- inventions agreements, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know- how and other non **-** patented technology. ~~44We~~ **We** may have to resort to litigation to protect our rights for certain intellectual property or to determine the scope, validity or enforceability of our intellectual property rights. Enforcing or defending our rights would be expensive, could cause diversion of our resources, and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products. Risks Related to Our EmployeesWe rely on a small number of key personnel who may terminate their employment with us at any time, and our success will depend on our ability to hire additional qualified personnel. Our success depends to a significant degree on the continued services of our executive officers, including our Chief Executive Officer, James V. Caruso. Our management and other employees may voluntarily terminate their employment with us at any time, and there can be no assurance that these individuals will continue to provide services to us. Our success will depend on our ability to attract and retain highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources. ~~Confidentiality~~ **43Confidentiality** agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete. We operate in the highly technical field of research and development of small- molecule drugs and rely, in part, on trade- secret protection in order to protect our proprietary trade secrets and unpatented know- how. However, trade secrets are difficult to protect, and we cannot be certain that our competitors will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know- how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party' s relationship with us. Also, we typically obtain agreements from these parties that inventions conceived by them in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party has illegally obtained, and is using our trade secrets or know- how, is difficult, expensive **,** and time- consuming, and the outcome is unpredictable. In addition, courts outside the U. S. may be less willing to protect trade secrets or know- how. The failure to obtain or maintain trade- secret protection could adversely affect our competitive position. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their current or former employers. As is common in the biotechnology and pharmaceutical industry, we engage individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors or who are employed by academic research institutions. Although no claims against us are currently pending, we may be subject to claims that we, or these employees, have used or disclosed trade secrets or other proprietary information of their current or former employers, either inadvertently or otherwise. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Risks Related to Commercialization of our ProductsAcceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues. Our future financial performance will depend, at least in part, on the introduction and customer acceptance of our proposed products. Even if approved for marketing by the necessary regulatory authorities, our products may not achieve market acceptance. The degree of market acceptance will depend on **several** ~~a number of~~ factors **,** including: ● receiving regulatory clearance of marketing claims for the uses that we are developing; ● the timing of market introduction of the product as well as competitive products; ~~45~~ ● the clinical indications for which the product is approved; ● establishing and demonstrating the advantages, safety and efficacy of our technologies; ● relative convenience and ease of administration, and the convenience of prescribing, administrating and initiating patients on the product and the length of time the patient is on the product; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the willingness of physicians to change their current treatment practices; ● the willingness of hospitals and hospital systems to include our product candidates as treatment options; ● demonstration of efficacy and safety in clinical trials; ● the prevalence and severity of any side effects; **44** ● the ability to offer product candidates for sale at competitive prices; ● the price we charge for our product candidates; ● the strength of marketing and distribution support; ● impacts ~~due to~~ **resulting from** the evolving effects of the COVID- 19 pandemic; ● the ability to distinguish safety and efficacy from existing, less expensive generic alternative therapies, if any; ● the potential and perceived value and advantages of the product over alternative treatments; ● the cost of treatment in relation to alternative treatments, including any similar generic treatments; ● pricing and reimbursement policies of government and third- party payors such as insurance companies, health maintenance organizations and other health plan administrators; ● attracting corporate partners, including pharmaceutical companies, to assist in commercializing our

intended products; and ● marketing our products. Physicians, patients, payors , or the medical community , in general, may be unwilling to accept, use , or recommend any of our products. If we are unable to obtain regulatory approval or commercialize and market our proposed products as planned, we may not achieve any market acceptance or generate revenue. If we are unable to sustain anticipated levels of sales growth from our products, if approved, we may need to reduce our operating expenses, access other sources of cash or otherwise modify our business plans, which could have a negative impact on our business, financial condition and results of operations. Regulatory approval for any approved product is limited by the FDA, the European Commission , and other regulators , to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may incur significant liability if it is determined that we are promoting the " off- label " use of any of our future product candidates if approved. Any regulatory approval is limited to those specific diseases, indications and patient populations for which a product is deemed to be safe and effective by the FDA, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency and other regulators. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected. 46While -- **While** physicians may choose to prescribe drugs for uses that are not described in the product' s labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications and patient populations that are specifically approved by the FDA or similar regulatory authorities in jurisdictions outside the U. S. These " off- label " uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. We have implemented compliance and monitoring policies and procedures, including a process for internal review of promotional materials, to deter the promotion for off- label uses. We cannot guarantee that these compliance activities will prevent or timely detect off- label promotion by sales representatives or other personnel in their communications with health care professionals, patients and others, particularly if these activities are concealed from the Company. Regulatory authorities in the US generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off- label use. If our promotional activities fail to comply with the FDA' s or other competent national authority' s regulations or guidelines, we may be subject to warnings from, or enforcement action by, these regulatory authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines, which could result in the disgorgement of money, operating restrictions, injunctions or civil or criminal enforcement, and other consequences, any of which could harm our business. Notwithstanding **45Notwithstanding** the regulatory restrictions on off- label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non- misleading and non- promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. If the FDA or other regulatory or enforcement authorities determine that our communications regarding our marketed product are not in compliance with the relevant regulatory requirements and that we have improperly promoted off- label uses, or that our communications regarding our investigational products are not in compliance with the relevant regulatory requirements and that we have improperly engaged in pre- approval promotion, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Any product for which we have obtained regulatory approval, or for which we obtain approval in the future, is subject to, or will be subject to, extensive ongoing regulatory requirements by the FDA, EMA and other comparable regulatory authorities, and if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, we may be subject to penalties, we may be unable to generate revenue from the sale of such products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased. Any product for which we have obtain regulatory approval in the future, along with the manufacturing processes and practices, post- approval clinical research, product labeling, advertising and promotional activities for such product, are subject to continual requirements of, and review by, the FDA, the EMA and other comparable international regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, current good manufacturing practices (cGMP) requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians, import and export requirements and recordkeeping. If we or our suppliers encounter manufacturing, quality or compliance difficulties with respect to any of our product candidates, when and if approved, whether ~~due to~~ **because of** the impacts of the ongoing COVID- 19 pandemic (including as a result of disruptions of global shipping and the transport of products) or otherwise, we may be unable to obtain or maintain regulatory approval or meet commercial demand for such products, which could adversely affect our business, financial conditions, results of operations and growth prospects. In addition, the FDA often requires post- marketing testing and surveillance to monitor the effects of products. The FDA, the EMA and other comparable international regulatory agencies may condition approval of our product candidates on the completion of such post- marketing clinical studies. These post- marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. Additionally, the FDA may require a REMS to help ensure that the benefits of the drug outweigh its risks. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug' s risks, limitations on who may prescribe or dispense the drug, requirements that patients enroll in a registry or undergo certain health evaluations or other measures that the FDA deems necessary to ensure the safe use of the drug. 47Discovery -- **Discovery** after approval of previously unknown problems with any of our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as: ● restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials ; ● restrictions on product manufacturing processes; ●

restrictions on the marketing of a product; ● restrictions on product distribution; ● requirements to conduct post- marketing clinical trials; ● untitled or warning letters or other adverse publicity; ● withdrawal of products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; **46** ● recall of products; ● refusal to permit the import or export of our products; ● product seizure; ● fines, restitution or disgorgement of profits or revenue; ● refusal to allow us to enter into supply contracts, including government contracts; ● injunctions; or ● imposition of civil or criminal penalties. If such regulatory actions are taken, the value of our company and our operating results will be adversely affected. Additionally, if the FDA, the EMA or any other comparable international regulatory agency withdraws its approval of a product that is or may be approved, we will be unable to generate revenue from the sale of that product in the relevant jurisdiction, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will be increased. Accordingly, we continue to expend significant time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, post- marketing studies and quality control. If any of our third- party contractors fail to perform their responsibilities to comply with FDA rules and regulations, the marketing and sales of our products could be delayed and we may be subject to enforcement action, which could decrease our revenues. Conducting our business requires us to manage relationships with third- party contractors. As a result, our success depends partially on the success of these third parties in performing their responsibilities to comply with FDA rules and regulations. Although we pre-qualify our contractors and we believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. If any of our partners or contractors fail to ~~perform~~ **fulfil** their obligations in an adequate and timely manner or fail to comply with the FDA' s rules and regulations, then the marketing and sales of our products could be delayed. The FDA may also take enforcement actions against us based on compliance issues identified with our contractors. If any of these events occur, we may incur significant liabilities, which could decrease our revenues. For example, sales and medical science liaison or MSL personnel, including contractors, must comply with FDA requirements for the advertisement and promotion of products. ~~48If~~ **If** manufacturers obtain approval for generic versions of our products, once approved, or of products with which we compete, our business may be harmed. Under the FDCA, the FDA can approve an abbreviated new drug application (ANDA) for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient (s), strength, dosage form and route of administration and that it is bioequivalent to the branded product. The FDCA requires that an applicant for approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the Orange Book or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon notice of a paragraph IV challenge, a patent owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner' s patents. If this type of suit is commenced, the FDCA provides a 30- month stay on the FDA' s approval of the competitor' s application. If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30- month stay period, the stay is lifted, and the FDA may thereafter approve the application based on the standards for approval of ANDAs. Once an ANDA is approved by the FDA, the generic manufacturer may market and sell the generic form of the branded drug in competition with the branded medicine. ~~The~~ **47The** ANDA process can result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner' s patents. If this were to occur with respect to iopofosine or any future products, once approved, with which our products ~~competes~~ **compete** , our business would be harmed. Unforeseen safety issues could emerge with our products, once approved, that could require us to change the prescribing information to add warnings, limit use of the product, and / or result in litigation. Any of these events could have a negative impact on our business. Discovery of unforeseen safety problems or increased focus on a known problem with respect to our products, once approved, could impact our ability to commercialize our products and could result in restrictions on its permissible uses, including withdrawal of the medicine from the market. If we or others identify additional undesirable side effects caused by our products after approval: ● regulatory authorities may require the addition of labeling statements, specific warnings, contraindications, or field alerts to physicians and pharmacies; ● regulatory authorities may withdraw their approval of the product and require us to take our approved drugs off the market; ● we may be required to change the way the product is administered, conduct additional clinical trials, change the labeling of the product, or implement a Risk Evaluation and Mitigation Strategy, or REMS; ● we may have limitations on how we promote our drugs; ● third- party payers may limit coverage or reimbursement for our products; ● sales of our approved products may decrease significantly; ● we may be subject to litigation or product liability claims; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of our products, once approved and could substantially increase our operating costs and expenses, which in turn could delay or prevent us from generating significant revenue from sale of any products for which we obtain approval. ~~49If~~ **If** a safety issue emerges post- approval, we may become subject to costly product liability litigation by our customers, their patients or payers. Product liability claims could divert management' s attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. If we cannot successfully defend ourselves against claims that our approved products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any product candidates or products that we may develop; ● the inability to commercialize any products that we may develop; ● injury to our reputation and significant negative media attention; ● withdrawal of patients from clinical studies or cancellation of studies; ● significant costs to defend the related litigation; ● substantial monetary awards to patients; and ● loss of revenue. ~~The~~ **48The** market for our proposed products is rapidly changing and competitive, and new therapeutics, drugs and treatments that may be developed by others could impair our ability to develop our business or become competitive. The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and proposed

products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and expected to increase. Most of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase our competitors' financial, marketing, manufacturing and other resources. Our resources are limited, and we may experience management, operational or technical challenges inherent in our activities and novel technologies. Competitors have developed, or are in the process of developing, technologies that are, or in the future may be, the basis for competition. Some of these technologies may accomplish therapeutic effects similar to those of our technology, but through different means. Our competitors may develop drugs and drug delivery technologies that are more effective than our intended products and, therefore, present a serious competitive threat to us. The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our products even if they are commercialized. Many of our targeted diseases and conditions can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for widespread acceptance of our technologies and products if commercialized. ~~Due to~~ **As a result of** continued changes in marketing, sales and distribution, we may be unsuccessful in our efforts to sell our proposed products, develop a direct sales organization, or enter into relationships with third parties. We have not established marketing, sales or distribution capabilities for our proposed products. Until such time as our proposed products are further along in the development process, we will not devote any meaningful time and resources to this effort. At the appropriate time, we will determine whether we will develop our own sales and marketing capabilities or enter into agreements with third parties to sell our products. We have limited experience in developing, training or managing a sales force. If we choose to establish a direct sales force, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a sales force on a cost- effective basis or at all. In addition, we will compete with many other companies that currently have extensive marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a cost- effective or timely basis, if at all. ~~50If~~ **If** we choose to enter into agreements with third parties to sell our proposed products, we may be unable to establish or maintain third- party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors. We may be unable to engage qualified distributors. Even if engaged, these distributors may: ● fail to adequately market our products; ● fail to satisfy financial or contractual obligations to us; ● offer, design, manufacture or promote competing products; or ● cease operations with little or no notice. If we fail to develop sales, marketing and distribution channels, we would experience delays in product sales and incur increased costs, which would have a material adverse effect on our business, prospects, financial condition and results of operation. ~~If~~ **49If** we are unable to convince physicians of the benefits of our intended products, we may incur delays or additional expense in our attempt to establish market acceptance. Achieving use of our products in the target market of cancer diagnosis and treatment may require physicians to be informed regarding these products and their intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this physician education process may adversely affect market acceptance of our proposed products. We may be unable to educate physicians, in sufficient numbers, in a timely manner regarding our intended proposed products to achieve our marketing plans and product acceptance. Any delay in physician education may materially delay or reduce demand for our proposed products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our proposed products is created, if at all. Efforts to educate the physicians, patients, healthcare payors and others in the medical community on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates are approved, if at all, but do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable on a sustained basis. If our products are unable to obtain adequate reimbursement from third- party payors, or if additional healthcare reform measures are adopted, it could hinder or prevent the commercial success of our product candidates. The commercial success of any product for which we obtain regulatory approval in the future will depend substantially on the extent to which the costs of our product or product candidates are or will be paid by third- party payors, including government health care programs and private health insurers. There is a significant trend in the health care industry by public and private payers to contain or reduce their costs, including by taking the following steps, among others: decreasing the portion of costs payers will cover, ceasing to provide full payment for certain products depending on outcomes or not covering certain products at all. If payers implement any of the foregoing with respect to our products, it would have an adverse impact on our revenue and results of operations. If coverage is not available, or reimbursement is limited, we, or any of our collaborative partners, may not be able to successfully commercialize our product candidates in some jurisdictions. Even if coverage is provided, the approved reimbursement amount may not be at a rate that covers our costs, including research, development, manufacture, sale and distribution. In the U. S., no uniform policy of coverage and reimbursement for products exists among third- party payors; therefore, coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific, clinical or other support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. ~~51In~~ **In** both the U. S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. For example, the Affordable Care Act which was passed in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, has been subject to judicial, legislative, and regulatory efforts to replace it or to alter its interpretation or implementation. Congress has considered

legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been enacted. The Tax Cuts and Jobs Act of 2017 included a provision that repealed the tax- based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate ". In addition, the Further the Consolidated Appropriations Act of 2020 fully repealed the Affordable Care Act' s mandated " Cadillac " tax on high- cost employer-sponsored health coverage and medical device tax and also eliminated the health insurer tax. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the law. It is unclear how future actions before the Supreme Court, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act. Other legislative changes have been proposed and adopted in the U. S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2 % per fiscal year, which went into effect in April 2013, and, ~~due to~~ **a result of** subsequent legislative amendments, will remain in effect into 2031, unless additional Congressional action is ~~taken~~ **50taken** . However, COVID- 19 relief support legislation suspended the 2 % Medicare sequester from May 1, 2020 through March 31, 2022 with a subsequent reduction to 1 % implemented from April 1, 2022 until June 30, 2022 **.** To offset the temporary suspension during the COVID- 19 pandemic, in 2030, reductions in Medicare payments will be 2. 25 % for the first half of the year, and 3 % in the second half of the year. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (ATRA), which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and may affect the prices we may set. In the U. S., there have been several recent Congressional inquiries and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer- sponsored patient assistance programs, and reform government program reimbursement methodologies for drugs. See Part I, Item 1, Business- Regulation- Reimbursement and Pricing Controls for more information on recent healthcare reform measures that may affect our ability to operate. We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. However, we expect these initiatives to increase pressure on drug pricing. Further, certain broader legislation that is not targeted to the health care industry may nonetheless adversely affect our profitability. Any additional healthcare reform measures could limit the amounts that the U. S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. ~~52We~~ **We** may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other federal and state healthcare laws, and the failure to comply with such laws could result in substantial penalties. Our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payers and customers, may expose us to broadly applicable federal, state and foreign fraud and abuse and other healthcare laws and regulations including anti-kickback and false claims laws, data privacy and security laws, and transparency reporting laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product for which we have obtained regulatory approval, or for which we obtain regulatory approval in the future. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations intended to prevent fraud, misconduct, bribery kickbacks, self- dealing and other abusive or inappropriate practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including promoting off- label uses of our products, commission compensation, certain customer incentive programs, certain patient support offerings, and other business arrangements generally. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of patient recruitment for clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. See " Part I, Item 1, Business – Regulation – Other U. S. Regulatory Requirements " of this Annual Report on Form 10- K for more information on the healthcare laws and regulations that may affect our ability to operate. We are also exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the US and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose

unauthorized ~~activities~~ **51activities** to us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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. We are also subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. Efforts to ensure that our business arrangements will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. ~~53Risks~~ -- **Risks** Related to Internal ControlsFailure to maintain effective internal controls could adversely affect our ability to meet our reporting requirements. We are required to establish and maintain appropriate internal controls over financial reporting. Rules adopted by the SEC pursuant to Section 404 of the Sarbanes- Oxley Act of 2002 require an annual assessment of internal controls over financial reporting and for certain issuers an attestation of this assessment by the issuer' s independent registered public accounting firm. The standards to assess that our internal controls over financial reporting are effective are evolving and complex, require significant documentation and testing, and may require remediation if they are not met. We expect to incur significant expenses and to devote resources to Section 404 compliance on an ongoing basis. It is difficult for us to predict how long it will take or costly it will be to complete the assessment of the effectiveness of our internal control over financial reporting for each year and to remediate any deficiencies in our internal control over financial reporting. As a result, we may not be able to complete the assessment and remediation process on a timely basis. In addition, although attestation requirements by our independent registered public accounting firm are not presently applicable to us, we could become subject to these requirements in the future, and we may encounter problems or delays in completing the implementation of any resulting changes to internal controls over financial reporting. Effective internal controls are necessary for us to provide reasonable assurance with respect to our financial reports and to effectively prevent fraud. Failure to maintain effective internal controls could adversely affect our public disclosures regarding our business, prospects, financial condition **,** or results of operations. In addition, management' s assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting or disclosure of management' s assessment of our internal controls over financial reporting our business and results of operations could be harmed, we could fail to meet our reporting obligations, and there could be a material adverse effect on our common stock price **. In 2023, three material weaknesses have been identified that are described further in Item 9A. below** . Risks Related to Our Equity SecuritiesFailure to meet Nasdaq' s continued listing requirements could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital. If our common stock becomes subject to delisting, it would be subject to rules that impose additional sales practice requirements on broker- dealers who sell our securities. The additional burdens imposed upon broker- dealers by these requirements could discourage broker- dealers from effecting transactions in our common stock. This would adversely affect the ability of investors to trade our common stock and would adversely affect the value of our common stock. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our common stock. If we seek to implement a further reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock. ~~Our~~ **52Our** stock price has experienced price fluctuations. There can be no assurance that the market price for our common stock will remain at its current level, and a decrease in the market price could result in substantial losses for investors. The market price of our common stock may be significantly affected by one or more of the following factors: ● announcements or press releases relating to the biopharmaceutical sector or to our own business or prospects; ● regulatory, legislative or other developments affecting us or the healthcare industry generally; ● sales by holders of restricted securities pursuant to effective registration statements or exemptions from registration; ● market conditions specific to biopharmaceutical companies, the healthcare industry and the stock market generally; and ● our ability to maintain our listing on the Nasdaq exchange. ~~54Our~~ -- **Our** common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options. In the past, we have issued common stock, convertible securities (such as convertible preferred stock and notes payable) and warrants ~~in order~~ to raise capital. We have also issued equity as compensation for services and incentive compensation for our employees and directors. We have shares of common stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, convertible securities, options and warrants could dilute our common stock, affect the rights of our stockholders, reduce the market price of our common stock, result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our common stock), or obligate us to issue additional shares of common stock to certain of our stockholders. Provisions of our certificate of incorporation, by- laws, and Delaware law may make an acquisition of us or a change in our management more difficult. Certain provisions of our certificate of incorporation and by- laws could discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which an investor might otherwise receive a premium for its shares. These provisions also could limit the price that investors might be willing to

pay in the future for shares of our common stock or warrants, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions: ● provide for the division of the Board into three classes as nearly equal in size as possible with staggered three- year terms and further limit the removal of directors and the filling of vacancies; ● authorize our Board to issue without stockholder approval blank- check preferred stock that, if issued, could operate as a " poison pill " to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board; ● require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent; ● establish advance notice requirements for stockholder nominations to our Board or for stockholder proposals that can be acted on at stockholder meetings; ● limit who may call stockholder meetings; ~~and~~ **and53** ~~● require the approval of the holders of 75 % of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our certificate of incorporation. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15 % or more of our outstanding voting stock, from merging or combining with us for a prescribed period of time. Item 2. Properties. We lease administrative office space in Florham Park, New Jersey and Middleton, Wisconsin. On December 30, 2022, we entered into an Amended Agreement of Lease (the " Amended Lease "), with Campus 100 LLC for the Florham Park space. The space in New Jersey consists of approximately 4, 000 square feet and is rented for approximately $ 12, 100 per month under an agreement that expires on April 30, 2029, subject to one additional five- year extension. The space in Wisconsin consists of approximately 300 square feet and is rented for approximately $ 3, 100 per month under an agreement that expires on December 31, 2023. 55~~