Risk Factors Comparison 2024-03-28 to 2023-03-23 Form: 10-K

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An investment in our common stock involves a high degree of risk. A prospective investor should carefully consider the following information about these risks, together with other information appearing elsewhere in this Annual Report on Form 10-K, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future prospects and prospective investors could lose all or part of their investment. The risk factors discussed below and elsewhere in this Annual Report on Form 10- K are not exhaustive; other significant risks may exist that are not identified in this Annual Report on Form 10- K, but that might still materially and adversely affect our business, prospects, financial condition, and results of operations were any of such risks to occur. Risks Related to Our Financial Condition and Capital Requirements We have a limited operating history, expect to incur significant operating losses, and have a high risk of never being profitable. We commenced operations in December 2014 and have an operating history of approximately ~~eight~~ **nine** years. Therefore, there is limited historical financial or operational information upon which to evaluate our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early clinical stages of operations. Many, if not most, companies in our industry at our stage of development never become profitable and are acquired, merge, sell major product assets or go out of business before successfully developing any product that generates revenue from commercial sales and enables profitability. From inception in December 2014 through December 31, ~~2022~~ **2023**, we have incurred losses of approximately $ ~~51~~ **60**. ~~8~~ **2** million, which includes $ 13. 5 million of non- cash in- process research and development, which was incurred in connection with our 2017 acquisition of camsirubicin. We expect to continue to incur substantial operating losses over the next several years for the clinical development of our current and future licensed or purchased product candidates and will continue to incur losses for the foreseeable future. We expect that our R & D and G & A expenses will increase to enable the execution of our strategic plan. As a result, we anticipate that we will seek to raise additional capital within the next 12 months to fund our future operations. We will seek to obtain needed capital through a combination of equity offerings, including **at-** the **- market** ~~usage of our Capital on DemandTM Sales~~ **sales programs** ~~Agreement with JonesTrading~~, debt financings, strategic collaborations and grant funding. To date, we have funded our operations through net proceeds from the initial public offering of our common stock, net proceeds from sales of our common stock through ~~an~~ at- the- market sales ~~program~~ **programs**, private placements of our preferred and common stock, and the net receipt of funds related to our acquisition of camsirubicin and related assets. The amount of future losses and when, if ever, we will become profitable are uncertain. We do not have any products that have generated revenues from commercial sales, and do not expect to generate revenues from the commercial sale of products in the near future, if ever. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the development of our product candidates; obtaining necessary regulatory approvals from the FDA and international regulatory agencies; establishing manufacturing / quality, sales, and marketing and distribution arrangements with third parties; obtaining adequate reimbursement by third- party payers; and raising sufficient funds to finance our activities. If we are unsuccessful at some or all of these undertakings, our business, financial condition, and results of operations are expected to be materially and adversely affected. ~~30We~~ **We** will need to raise substantial additional funding or find ~~a~~ **one or more** suitable pharmaceutical ~~partner~~ **partners** to continue to advance our clinical programs and support our preclinical activities. In order to be commercially viable, we must successfully research, develop, test, obtain regulatory approval for, manufacture, introduce, market and distribute **some or all** ~~Validive, camsirubicin,~~ MNPR- 101- Zr, MNPR- 101 RIT, **camsirubicin, and** MNPR- 202, and, if applicable, any **other** ~~current and future~~ product candidates we may develop. The estimated required capital and time- frames necessary to achieve these developmental milestones as described in this Annual Report on Form 10- K or as we may state from time to time ~~is~~ **are** subject to inherent risks, which are beyond our control. Clinical development of ~~Validive, camsirubicin,~~ MNPR- 101- Zr, MNPR- 101 RIT, **camsirubicin** and MNPR- 202 will require significant funds. Proceeds to- date from the sales of our common stock we believe could be sufficient for us to complete our **planned Phase 1 dosimetry trial of MNPR- 101- Zr, continued development of MNPR- 101- RIT and the** ongoing open- label Phase 1b camsirubicin clinical trial ~~(but this may not be the case if camsirubicin reaches even higher dose levels than we are anticipating) and, assuming a positive result of the go / no go interim analysis decision anticipated by the end of March 2023, continue enrolling the Phase 3 portion of our ongoing Validive Phase 2b / 3 (VOICE) clinical program~~, but will not be sufficient for us to **support additional** ~~complete our VOICE~~ clinical ~~program, including if we need to run a second confirmatory Phase 3~~ **development of MNPR- 101 for radiopharmaceutical use in advanced cancers and camsirubicin** clinical ~~trial and support further~~ development ~~through and~~ beyond ~~our ongoing~~ Phase 1b **. To complete the MNPR- 101 radiopharmaceutical and** camsirubicin clinical ~~trial. To complete the VOICE clinical program~~ **programs**, ~~including, if required, completing a second Phase 3 confirmatory clinical trial,~~ we will need to raise additional funding in the ~~millions or~~ tens of millions of dollars. Therefore, we will need to raise significant additional funds or find a suitable pharmaceutical partner within the next 12 months to ~~complete the VOICE clinical program, as well as support further development of camsirubicin through and beyond our ongoing Phase 1b, to support MNPR- 101- Zr, MNPR- 101 RIT and MNPR- 202 and related compounds in various indications and generally to~~ support our current and any future product candidates through completion of clinical trials, approval processes and, if applicable, commercialization ~~,~~ **.** If we are able to raise financing, it may be on terms that are unfavorable to us and if we are unable to raise sufficient funds or find a suitable pharmaceutical partner, we may have to discontinue or delay clinical development of ~~Validive and / or any other of~~ our current

or future product candidates. If the interim analysis for our ongoing..... therapeutics to treat COVID- 19. The Russia- Ukraine **war and / or the Israel- Hamas** war will likely have continuing global effects on fuel costs and shipping and broader impacts on economic, trade and financial market conditions, which could delay the shipping of supplies for our clinical material manufacturing, potentially resulting in increased manufacturing expenses, delays to our clinical programs and adverse effects on our financing activities and financial condition. The Russia- Ukraine war ~~is a~~ **and the Israel- Hamas war are** volatile ~~situation~~ **situations** , resulting in financial services and banking instability in the **respective** ~~region~~ **regions** . The U. S. and other countries' sanctions against Russia and Russian entities, together with existing inflationary conditions and supply chain challenges arising in the wake of ~~COVID~~ **the Israel** - ~~19~~ **Hamas war** , are affecting fuel costs and shipping, resulting in higher costs and delays for various types of supplies. These cost increases and delays may affect our clinical material manufacturing which will likely have an adverse effect on our financial condition. In addition, at this stage, we are unable to predict whether the ~~war~~ **wars and resulting instability** will have broader adverse impacts to European, U. S. or global economic, trade and financial market conditions, which could adversely affect our operations and financial condition in a variety of ways. In particular, financial market instability or volatility may make it more difficult to raise required financing. If we continue to incur operating losses and fail to obtain the capital necessary to fund our operations, we will be unable to advance our development programs, complete our clinical trials, or bring products to market, or may be forced to reduce or cease operations entirely. In addition, any capital obtained by us may be obtained on terms that are unfavorable to us, our investors, or both. ~~32While~~ -- **While** we believe adequate cash is currently available to operate ~~for the next twelve months~~ **at least through June 30, 2025** , developing a new drug and conducting clinical trials and the regulatory review processes for one or more disease indications involves substantial costs. We have projected cash requirements for the near term based on a variety of assumptions, but some or all of such assumptions are likely to be incorrect and / or incomplete, possibly materially in an adverse direction. Our actual cash needs may deviate materially from those projections, changes in market conditions or other factors may increase our cash requirements, or we may not be successful even in raising the amount of cash we currently project will be required for the near term. We will need to raise additional capital in the future ; the amount of additional capital needed will vary as a result of a number of factors, including without limitation the following: ● receiving less funding than we require; ● higher than expected costs to manufacture and ship our active pharmaceutical ingredient **, radioisotopes,** and our product candidates; ● higher than expected costs for preclinical testing; ● **the cost and availability of radioisotopes such as Ac- 225 or Zr- 89, or any other medical isotope we may incorporate into our product candidates; ●** an increase in the number, size, duration, and / or complexity of our clinical trials; ● slower than expected progress in developing ~~Validive~~ **our MNPR- 101 radiopharmaceutical program** , camsirubicin, **and** ~~MNPR- 101- Zr, MNPR- 101 RIT,~~ MNPR- 202 or other product candidates, including without limitation, additional costs caused by program delays; ● higher than expected costs associated with attempting to obtain regulatory approvals, including without limitation additional costs caused by additional regulatory requirements or larger clinical trial requirements; ● higher than expected personnel, consulting or other costs, such as adding personnel or industry expert consultants or pursuing the licensing / acquisition of additional assets; and ● higher than expected costs to protect our intellectual property portfolio or otherwise pursue our intellectual property strategy. When we attempt to raise additional financing, there can be no assurance that we will be able to secure such additional financing in sufficient quantities or at all. We may be unable to raise additional capital for reasons including, without limitation, our operational and / or financial performance, investor confidence in us and the biopharmaceutical industry, credit availability from banks and other financial institutions, the status of current projects, and our prospects for obtaining any necessary regulatory approvals. General economic and financial market conditions, which have recently been impacted by inflation, bank instability and other factors, can also adversely impact our ability to raise additional financing. Potential investors' capital investments may have shifted to other opportunities with perceived greater returns and / or lower risk, thereby reducing capital available to us, if available at all. In addition, any additional financing might not be available, and even if available, may not be available on terms acceptable to us or our then- existing investors. We will seek to raise funds through public or private equity offerings, including **at-** the **-market** ~~usage of our Capital on DemandTM Sales~~ **sales programs** ~~Agreement with JonesTrading~~ , debt financings, corporate collaboration or licensing arrangements, mergers, acquisitions, sales of intellectual property, or other financing vehicles or arrangements. To the extent that we raise additional capital by issuing equity securities or other securities, our then- existing investors will experience dilution. If we raise funds through debt financings or bank loans, we may become subject to restrictive covenants, our assets may be pledged as collateral for the debt, and the interests of our then- existing investors would be subordinated to the debt holders or banks. In addition, our use of and ability to exploit assets pledged as collateral for debt or loans may be restricted or forfeited. To the extent that we raise additional funds through collaboration or licensing arrangements, we may be required to relinquish significant rights (including without limitation intellectual property rights) to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are not able to raise needed funding under acceptable terms or at all, then we will have to reduce expenses, including the possible options of curtailing operations, abandoning opportunities, licensing or selling off assets, reducing costs to a point where clinical development or other progress is impaired, or ceasing operations entirely. ~~33Market~~ -- **Market** variables, such as inflation of product costs, labor rates and fuel, freight and energy costs, as well as geopolitical events could likely cause us to suffer significant increases in our operating and administrative expenses. In the wake of the COVID- 19 pandemic, the Russia- Ukraine **war, the Israel- Hamas** war and other geopolitical factors, economic conditions have become strained, with inflation and supply chain challenges impacting businesses worldwide. These conditions affect fuel costs and shipping, resulting in higher costs and delays for various types of supplies. These cost increases and delays may affect our clinical material manufacturing which will likely have an adverse effect on our financial condition. In addition, the effects of responses to inflationary conditions, such as significantly increased interest rates, on the economy and market conditions are difficult to predict. If U. S. or global economic, trade and financial market conditions continue to be challenged or volatile, or we do not effectively manage our response to

these conditions, our operations and financial condition could be adversely affected in a variety of ways. Unstable market and economic conditions may have serious adverse consequences on our ability to raise funds, which may cause us to delay, restructure or cease our operations. From time to time, global and domestic credit and financial markets have experienced extreme disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. Recently, COVID- 19 ~~and~~ **,** the Russia- Ukraine **war and the Israel- Hamas** war have created volatility and uncertainty. Recent instability in the banking industry has added to the volatility and uncertainty. Our financing strategy will be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, it may make a debt or equity financing more difficult to complete, costlier, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms will have a material adverse effect on our business strategy and financial performance, and could require us to cease or delay our operations. ~~12 months.There can~~ **Our operations and financial results could** be **adversely impacted by resurgences** ~~no assurance that any such events will occur,and the long- term effects~~ of COVID- 19 ~~continue to create uncertainties and challenges to~~ **or any future pandemics,which may negatively impact** our ability to ~~seek additional funding~~ **manufacture our product candidates for our clinical trials,our ability to accrue** and ~~explore collaborations~~ **conduct our clinical trials,** and ~~partnerships~~ **may delay regulatory agency responses** . ~~While we are currently continuing~~ **Any such impact will negatively impact** our ~~ongoing~~ **financial condition and could require us to delay our** clinical ~~trials,~~ **development programs.If there is a resurgence of** COVID- 19 ~~and related precautions have directly or indirectly impacted the timeline for~~ **or any future pandemics** ~~certain of our clinical trials.We are~~ **arise** ~~continuing to monitor the impact of COVID- 19 on our operations and ongoing clinical development activity,generally.As a result of COVID- 19~~ ,we may experience ~~further~~ disruptions that could severely impact our business,preclinical studies and clinical trials,including:● Delays in receiving approval from the FDA **,the TGA in Australia** and **other** foreign regulatory authorities to initiate our planned clinical trials;● Delays or difficulties in enrolling and monitoring patients in our clinical trials;● Delays or difficulties in clinical site initiation,including difficulties in recruiting clinical site investigators and clinical site staff;● Delays in trial drug shipments due to ~~COVID- 19~~ vaccine shipments tying up available pharmaceutical product shipping lanes and increasing their cost; ~~31~~ ● Diversion of healthcare resources away from the conduct of clinical trials,including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;● Risk that participants enrolled in our clinical trials will acquire **diseases** ~~COVID- 19~~ while the clinical trial is ongoing,which could impact the results of the clinical trial,including by increasing the number of observed adverse events;● Interruption of key clinical trial activities,such as clinical trial site data monitoring,due to limitations on travel imposed or recommended by federal or state governments,employers and others or interruption of clinical trial subject visits and study procedures,which may impact the integrity of subject data and clinical study endpoints;● Interruption or delays in the operations of the FDA **,the TGA,** and **other** foreign regulatory agencies,which may impact approval timelines;● Interruption of,or delays in receiving,supplies of our product candidates from our contract manufacturing organizations due to staffing or supply shortages,production slowdowns,global shipping delays or stoppages and disruptions in delivery systems;● Limitation on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials,including because of sickness of our employees or their families or the desire of employees to avoid contact with large groups of people.● Refusal of the FDA **,the TGA,and other foreign regulatory authorities** to accept data from clinical trials in affected geographies;and ● Impacts from prolonged remote work arrangements,such as increased cybersecurity risks.The extent to which the long- term effects of COVID- 19 **or any future pandemics** further ~~impacts~~ **impact** our business,including our preclinical studies and clinical trials,results of operations and financial condition will depend on future developments which remain highly uncertain and cannot be predicted with confidence. ~~Such~~ Risks Related to Clinical Development and Regulatory Approval **Radiopharmaceuticals are a relatively novel approach to cancer imaging and treatment, which may create significant and potentially unpredictable challenges for it. Our future success depends on the successful development of our product candidates, including MNPR- 101 for radiopharmaceutical use and any future radiopharmaceutical agent (s) that we may develop in- house, in- license or acquire, which are designed to image, identify or treat cancers by targeted delivery of radioisotopes to tumors. While radiation as a therapy for cancers has existed for decades, oncology treatment using systemic delivery of targeted radiopharmaceuticals in general is relatively new. Only a few therapies utilizing systemic delivery of radioisotopes have been approved globally, and only a limited number of clinical trials of products based on radioisotope therapies have been conducted. There are currently no approved therapies which use Ac- 225, which we are exploring with MNPR- 101. Global supply of Ac- 225 is also currently limited and may not be capable of expanding sufficiently to provide the amounts required at commercial scale. As such, it is difficult to accurately predict the developmental challenges that the Company may incur for its product candidates as they proceed through product discovery or identification, preclinical studies and clinical trials, and, if approved, commercialization. In addition, there may be long- term effects from radiopharmaceutical treatment, including late radiation toxicity, with any of the Company' s current or future product radiopharmaceutical candidates that it cannot predict at this time. It is difficult for us to predict the time and cost of the development of our product candidates. Any of these factors may prevent the Company from completing our preclinical and clinical trials that we may initiate, or from commercializing any product candidates we may develop on a timely or profitable basis, if at all. In addition, the success of the Company' s current and future radiopharmaceutical programs will depend on several factors, including the following: ● sourcing clinical and, if approved for commercialization, commercial supplies for the materials, such as radioisotopes, used to manufacture our product candidates; ● sourcing or establishing manufacturing capabilities to produce adequate amounts of our product candidates; ● securing reliable supply chain for our product candidates given that isotope half- life times are limited; ● utilizing imaging agents to visualize tumor uptake in advance of administering our therapeutic**

candidates, which may increase the risk of adverse side effects; ● facilitating patient access to the limited number of facilities able to administer our product candidates; ● using medicines to manage adverse side effects of our drug candidates that may not adequately control the side effects or that may have detrimental impacts on the efficacy of the treatment; and ● establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of the Company' s novel radiopharmaceutical imaging and therapeutics. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources, and approvals are inherently uncertain. If any of our radiopharmaceutical program product candidates are approved, their commercial success will depend upon competitive products, public perception of radioisotopes and the degree of their market acceptance by physicians, patients, healthcare payors and others in the medical community. Adverse events in clinical trials of our product candidates or in clinical trials of others developing radiopharmaceuticals or similar agents and the resulting negative publicity, as well as any other adverse events in the field of radiopharmaceuticals that may occur in the future, could result in a decrease in demand for our product candidates. Also, future success of our drug candidates, if approved will depend on gaining and maintaining acceptance by physicians, patients, third- party payors and other members of the medical community as their being efficacious and cost- effective alternatives to competing products and treatments. Due to the radioactive nature of MNPR- 101- Zr and MNPR- 101 therapeutic agents, as well as our future radiopharmaceutical candidates, once manufactured, our drug candidates will have time- limited stability, and as a result, we may encounter difficulties with fulfilment and logistics. If we or our manufacturers are unable to meet the challenges posed by the time- limitations inherent in the composition of our MNPR- 101 radiopharmaceutical program or any of our future drug candidates, it would adversely affect our business, financial condition, results of operations and prospects. We expect our other radiopharmaceutical drug candidates to also have time- limited stability. As such, our drug candidates, including MNPR- 101 radiopharmaceutical program, must be manufactured on an as- needed basis, and shipped almost immediately thereafter. Because our drug candidates, including our MNPR- 101 radiopharmaceutical program, cannot be " stockpiled " and stored for even a small number of days ahead of shipment, we or any third- party manufacturer must be able to manufacture our drug candidates on a rolling basis, and any kind of delays, even if seemingly insignificant, could result in an immediate and substantial impact on our ability to deliver the drug candidate to patients. Any significant delays in delivering drug candidates to patients could damage our reputation and result in deviations from our clinical trial protocols, which in turn could affect our ability to advance the preclinical and clinical development of our MNPR- 101 radiopharmaceutical program or our other current and future radiopharmaceutical candidates on a timely basis, or at all. We do not currently maintain a manufacturing facility, and therefore we currently rely on third- party manufacturers for the production of our MNPR- 101 radiopharmaceutical program in connection with our ongoing studies. We cannot be sure that such manufacturers will be able to meet our demand for our radiopharmaceutical programs on a timely basis. In addition, once manufactured, our MNPR- 101 radiopharmaceutical program and future radiopharmaceutical drug candidates in the clinic must be quickly and safely transported to the applicable clinical trial site. As we scale our operations and enroll larger clinical trials, and prepare for potential commercialization, we will need to scale our shipping capabilities. Labor disputes, government restrictions, work stoppages, pandemics, derailments, damage or loss events, adverse weather conditions, and other events beyond our control could interrupt or delay transportation, which could result in the damage to our MNPR- 101 radiopharmaceutical program or any current or future drug candidate with similar shelf- life restrictions. If we or our manufacturers are unable to meet the challenges posed by the time- limitations inherent in the composition of our MNPR- 101 radiopharmaceutical program or any of our current or future drug candidates, it would adversely affect our business, financial condition, results of operations and prospects. Perceptions of these challenges and risks in the market may adversely impact our stock price and our ability to successfully raise funding as we focus our preclinical and clinical efforts on our radiopharmaceutical program. We do not have and may never have any approved products on the market. Our business is highly dependent upon receiving approvals from various U. S. **, Australian,** and international governmental agencies and will be severely harmed if we are not granted approval to manufacture and sell our product candidates. In order for us to commercialize any treatment for ~~chemoradiation- induced SOM,~~ cancer or any other disease indication, we must obtain regulatory approvals of such treatment for that indication. Satisfying regulatory requirements is an expensive process that takes many years and involves compliance with requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use. To obtain necessary regulatory approvals, we must, among other requirements, complete clinical trials demonstrating that our products are safe and effective for a particular indication. There can be no assurance that our products will prove to be safe and effective, that our clinical trials will demonstrate the necessary safety and effectiveness of our product candidates, or that we will succeed in obtaining regulatory approval for any treatment we develop even if such safety and effectiveness are demonstrated. Any delays or difficulties we encounter in our clinical trials may delay or preclude regulatory approval from the FDA **,** or from international regulatory organizations. Any delay or preclusion of regulatory approval would be expected to delay or preclude the commercialization of our products. Examples of delays or difficulties that we may encounter in our clinical trials include **,** without limitation **.** the following: ● Clinical trials may not yield sufficiently conclusive results for regulatory agencies to approve the use of our products. ● Our products may fail to be more effective than current therapies, or to be effective at all. ● We may discover that our products have adverse side effects, which could cause our products to be delayed or precluded from receiving regulatory approval or reduce the effective size of our target patient population or otherwise expose us to significant commercial and legal risks. ● It may take longer than expected to determine whether or not a treatment is safe and effective. ● Patients involved in our clinical trials may suffer severe adverse side effects even up to death, whether as a result of treatment

with our products, the withholding of such treatment, or other reasons which may not include the effects of our treatment (whether within or outside of our control). ~~34~~ ● We may fail to be able to enroll a sufficient number of patients in our clinical trials to meet trial statistical plans and gain statistical significance, or it may take longer than expected to enroll. ● Patients enrolled in our clinical trials may not have the safety or efficacy characteristics necessary to obtain regulatory approval for a particular indication or patient population. ● We may be unable to produce sufficient quantities of product to complete the clinical trials. ● Even if we are successful in our clinical trials, required governmental approvals may still not be obtained or, if obtained, may not be maintained. ● If approval for commercialization is granted, it is possible the authorized use will be more limited than is necessary for commercial success, or that approval may be conditioned on completion of further clinical trials or other activities, which will cause a substantial increase in costs and which we might not succeed in performing or completing. ● If granted, approval may be withdrawn or limited if problems with our products emerge or are suggested by the data arising from their use or if there is a change in law or regulation. Any success we may achieve at a given stage of our clinical trials does not guarantee that we will achieve success at any subsequent stage, including without limitation final FDA or other regulatory organizations' approval. We may encounter delays or rejections in the regulatory approval process because of additional government regulation resulting from future legislation or administrative action, or from changes in the policies of the FDA or other regulatory bodies during the period of product development, clinical trials, or regulatory review. Failure to comply with applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production, or an injunction preventing certain activity, as well as other regulatory action against our product candidates or us. As a company, we have no experience in successfully obtaining regulatory approval for a product and thus may be poorly equipped to gauge, and may prove unable to manage, risks relating to obtaining such approval. Outside the U. S., our ability to market a product is contingent upon receiving clearances from appropriate non- U. S. regulatory authorities **, including the HREC in Australia** . Non- U. S. regulatory approval typically includes all of the risks associated with FDA clearance discussed above as well as geopolitical uncertainties and the additional uncertainties and potential prejudices faced by U. S. pharmaceutical companies conducting business abroad. In certain cases, governmental pricing restrictions and practices can make achieving even limited profitability very difficult. Even if we complete the clinical trials we discussed with the FDA **or TGA** , there is no guarantee that at the time of submission the FDA **or TGA** will accept our new drug application (" NDA ") **or biologics license application (" BLA")** based on the trials discussed ~~. The FDA provided guidance on our proposed VOICE trial, but the FDA is not bound by the guidance they give, and can change their position in the future~~ . Any future decision by the FDA **and TGA** will be driven largely by the data generated from ~~the VOICE clinical program~~ **our currently ongoing or any future planned trials** . However, the FDA and other regulatory organizations **, including the TGA,** will learn from their total experience in the review of multiple drugs in multiple indications and they will apply ~~the~~ **that** knowledge of broad and diverse experience even if less than a perfect match with our product **. If the FDA or TGA require additional clinical trials it will increase our costs, delay our potential path to commercialization and could materially affect our financial condition** . As a company, we have never completed a clinical trial and have limited experience in completing regulatory filings and any delays in regulatory filings could materially affect our financial condition. While members of our team have conducted numerous clinical trials at previous companies, and have launched and marketed innovative pharmaceutical products in the U. S. and internationally, as a company, we have not yet completed any clinical trials of our product candidates, nor have we demonstrated the ability to obtain marketing approvals, manufacture product candidates at a commercial scale, or conduct sales and marketing activities necessary for the successful commercialization of a product. Consequently, we have no historical basis as a company by which one can evaluate or predict reliably our future success or viability. ~~35Additionally~~ -- **Additionally** , while our team has experience at prior companies with regulatory filings, as a company, we have limited experience with regulatory filings with agencies such as the FDA **, TGA,** or EMA. Any delay in our regulatory filings for our product candidates, and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including, without limitation, the FDA' s issuance of a " refuse to file " letter or a request for additional information, could materially affect our financial condition. We ~~may seek fast track designation for one or more of our current and future product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process. Our lead product candidate, Validive, has been given fast track designation from the FDA. Fast track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development, regulatory review or approval process with fast track designation compared to conventional FDA procedures. Additionally, the FDA may withdraw fast track designation, for reasons such as it comes to believe a drug candidate no longer adequately addresses an unmet medical need. Fast track designation alone does not guarantee qualification for the FDA' s priority review procedures. If we seek fast track designation for other product candidates, we may not receive such a designation from the FDA. We~~ , or any future collaborators, may not be able to obtain and maintain orphan drug exclusivity for our product candidates in the U. S. and Europe ~~. Validive has been granted orphan drug designation for the treatment of SOM in the EU~~ . Camsirubicin has been granted orphan drug designation for the treatment of soft tissue sarcoma in the U. S. and in the EU. We may seek additional orphan drug designations or regulatory incentives for our pipeline product candidates, for other indications or for future product candidates. There can be no assurances that we will be able to obtain such designations. Even if we obtain orphan drug designation for a product candidate, we may not be able to maintain orphan drug exclusivity for that drug. For example **, in certain geographies** , orphan drug designation may be removed if the prevalence of an indication increases beyond the patient number limit required to maintain designation. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product in the same indication for that time period. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially

defective or if the manufacturer is unable to assure sufficient quantity at the specified quality of the product to meet the needs of patients with the rare disease or condition. Moreover, even after an orphan drug is approved, the FDA can subsequently approve a different drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared to our product. The FDA may reevaluate the Orphan Drug Act and its regulations and policies, and similarly the EMA may reevaluate its policies and regulations. We do not know if, when, or how the FDA or EMA may change their orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA and / or EMA may make to their orphan drug regulations and policies, our business could be adversely impacted. If serious adverse or undesirable side effects are identified during the development of our product candidates, we may abandon or limit our development or commercialization of such product candidates. If our product candidates are associated with undesirable side effects or have unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. If we elect to or are forced to suspend or terminate any clinical trial with one of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate revenue from such product candidate will be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly. 36With regard to our lead product candidate, unforeseen side effects from Validive could arise either during clinical development or, if approved, after Validive has been marketed. This could cause regulatory approvals for, or market acceptance of, Validive to be harder and costlier to obtain. To date, no difference in the frequency of serious adverse events (" SAEs ") has been observed in patients treated with Validive compared to placebo. In the Phase 2 clinical trial, two patients in the placebo group and 2 patients in the Validive 50 µg group experienced SAEs that were assessed as treatment related. No patients in the Validive treated cohorts were discontinued due to the study drug. Clonidine, the active ingredient of Validive, has been used for over 50 years as an orally swallowed systemic treatment for high blood pressure. Validive administration leads to very low, but still detectable exposure of clonidine outside the oral cavity. Thus, there is some risk that patients may experience side effects due to this systemic exposure, which could include a reduction in blood pressure, irregular heartbeat, drowsiness or dry mouth. The results of our current or any future clinical trials may show that the side effects of Validive are unacceptable or intolerable, which would interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or EMA and other regulatory authorities, or result in marketing approval from the FDA or EMA and other regulatory authorities with restrictive label warnings. If Validive receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by the use of Validive: ● regulatory authorities may withdraw their approval of the product, which would force us to remove Validive from the market; ● regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies; ● we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product; ● we may be subject to limitations on how we may promote the product; ● sales of the product 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 or our potential future collaborators from achieving or maintaining market acceptance of Validive and / or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of Validive. 37As with any clinical trial, our VOICE clinical program entails significant risk of not meeting clinical endpoints. If the results of VOICE are not statistically significant, the FDA will likely not approve Validive for marketing which will result in a decrease in our stock price and market value. The VOICE clinical program has been designed based on an analysis of the 64 oropharyngeal cancer (" OPC ") patients included in the Phase 2 trial (n = 24 in the placebo group, n = 21 Validive 50 µg group, and n = 19 Validive 100 µg group). While a dose response was observed in the Validive treated OPC cohorts compared to placebo across multiple clinically meaningful endpoints, the ability to establish statistical significance was limited by the relatively small sample size. This increases the risk that the VOICE trial may not achieve its prospectively defined endpoints. VOICE includes an interim analysis after the 2b portion that allows for an assessment of the primary (and only) endpoint, incidence of SOM, before proceeding to the Phase 3 portion of the trial. This interim analysis, and the resulting go / no- go decision about whether to proceed to the Phase 3 portion of the trial, is expected by the end of March 2023. If the interim analysis results in a no- go decision, we would need to reconsider our efforts with respect to Validive and refocus our development efforts on our other product candidates. Validive has been our lead product candidate to date and is the most clinically advanced, and if we had to reconsider or abandon our efforts, it would likely materially adversely impact our financing prospects, as well as the price of our common stock. Because the interim analysis is being performed by an independent data monitoring committee, we do not know what the results will be as of the date of this Annual Report. Assuming positive results from the interim analysis and that we fully proceed to the Phase 3 portion of the trial, we may also be required by the FDA to conduct a second Phase 3 confirmatory clinical trial which may not yield the same results. If our VOICE clinical trial results are not statistically significant, the FDA will likely not approve Validive for marketing, which will result in a decrease in our stock price and market value. If we experience delays or difficulties in the enrollment of subjects to our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented, which could materially affect our financial condition. Identifying, screening and enrolling patients to participate in clinical trials of our product candidates is critical to our success, and we may not be able to identify, recruit, enroll and dose a sufficient number of patients with the required or desired characteristics to complete our clinical trials in a timely manner. The timing of our clinical trials depends on our ability to recruit patients to participate as well as to subsequently dose these patients and complete required follow- up periods. In particular, because our current clinical trials of Validive and camsirubicin are focused on indications with relatively small patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. In addition, we may experience enrollment delays related to increased or unforeseen regulatory, legal and logistical requirements and COVID- 19-

related **or other future pandemic- related as well as** issues **related to currently ongoing or any future geopolitical risks** at certain clinical trial sites. These delays could be caused by reviews by regulatory authorities and contractual discussions with individual clinical trial sites. Any delays in enrolling and / or dosing patients in our current clinical trials could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or in termination of the clinical trials altogether. Patient enrollment may be affected if our competitors have ongoing clinical trials with products for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in our competitors' clinical trials. Patient enrollment may also be affected by other factors, including: ● delays in U. S. **, Australian** or **other** foreign regulatory approvals to start the clinical trial; ● coordination with **any** clinical research organizations to enroll and administer the clinical trials; ● coordination and recruitment of collaborators and investigators at individual sites; ● size of the patient population and the effectiveness of the process for identifying patients; ● design of the clinical trial protocol; ● eligibility and exclusion criteria; ● perceived therapeutic risks and benefits of the product candidates ~~under study~~ **being studied** ; ● availability of competing commercially available therapies and other competing products' clinical trials; ● time of year in which the trials are initiated or conducted; ● severity and prognosis of the diseases under investigation; ● ability to obtain and maintain subject consents; ● ability to enroll and treat patients in a timely manner; ● risk that enrolled subjects will drop out before completion of the trials; ● proximity and availability of clinical trial sites for prospective patients; ● ability to monitor subjects adequately during and after treatment; ● **logistical challenges posed by the time- limited shelf- life of our current or future drug candidates; ●** patient referral practices of physicians; and ● potential long- term effects of COVID- 19 **, any resurgences thereof or any future pandemics** . ~~38Our~~ -- **Our** inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which could materially affect our financial condition. If we or our licensees, development collaborators, or suppliers are unable to manufacture our products in sufficient quantities or at defined quality specifications, or are unable to obtain regulatory approvals for the manufacturing facility, we may be unable to develop and / or meet demand for our products and lose time to market and potential revenues. Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. We will utilize third parties to manufacture ~~Validive,~~ **our MNPR- 101 radiopharma program and** camsirubicin ~~, and MNPR- 101~~ . We currently have manufacturing arrangements for ~~Validive~~ **MNPR- 101- Zr** and camsirubicin **for clinical use** . We have not yet secured manufacturing agreements for MNPR- 101- ~~Zr,~~ **RIT or** MNPR- ~~101 RIT or MNPR-~~ 202 **for clinical use** . In the future we may become unable, for various reasons, to rely on our sources for the manufacture of our product candidates, either for clinical trials or, at some future date, for commercial distribution. We may not be successful in identifying additional or replacement third- party manufacturers, or in negotiating acceptable terms with any we do identify. We may face competition for access to these manufacturers' facilities and may be subject to manufacturing delays if the manufacturers give other clients higher priority than they give to us. Even if we are able to identify an additional or replacement third- party manufacturer, the delays and costs associated with establishing and maintaining a relationship with such manufacturer may have a material adverse effect on us. Before we can begin to commercially manufacture ~~Validive,~~ camsirubicin, MNPR- 101- Zr, MNPR- 101 RIT, MNPR- 202 or any other product candidate, we must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with current Good Manufacturing Practices requirements, commonly known as " cGMP. " The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non- U. S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to ensure that the product meets applicable specifications and other requirements. We, or our contracted manufacturing facility, must also pass a pre- approval inspection prior to FDA **or TGA** approval. Failure to pass a pre- approval inspection will likely significantly delay or prevent FDA **, TGA or other international regulatory agencies'** approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products and will lose time to market and potential revenues. It is uncertain whether product liability insurance will be adequate to address product liability claims, or that insurance against such claims will be affordable or available on acceptable terms in the future. Clinical research involves the testing of new drugs on human volunteers pursuant to a clinical trial protocol. Such testing involves a risk of liability for personal injury to or death of patients due to, among other causes, adverse side effects, improper administration of the new drug, or improper volunteer behavior. Claims may arise from patients, clinical trial volunteers, consumers, physicians, hospitals, companies, institutions, researchers, or others using, selling, or buying our products, as well as from governmental bodies including a possibility in some states for product liability claims being made based on generic copies of our drugs. In addition, product liability and related risks are likely to increase over time, in particular upon the commercialization or marketing of any products by us or parties with which we enter into development, marketing, or distribution collaborations. Although we have obtained product liability insurance in connection with our clinical trials, there can be no assurance that the amount and scope of such insurance coverage will be appropriate and sufficient in the event any claims arise, that we will be able to secure additional coverage should we attempt to do so, or that our insurers would not contest or refuse any attempt by us to collect on such insurance policies. Regardless of their merit or eventual outcome, product liability claims may result in: ~~39~~ ● withdrawal of clinical trial volunteers; ● decreased demand for our products when approved; ● injury to our reputation and significant, adverse media attention; and ● potentially significant litigation costs, including without limitation, any damages awarded to the plaintiffs if we lose or settle claims. If the market opportunities for our current and potential future drug candidates are smaller than we believe they are, our ability to generate product revenues will be adversely affected and our business may suffer. Our understanding of the number of ~~people~~ **patients** who ~~suffer from SOM resulting from CRT~~ **have advanced cancers that express uPAR and are eligible** for ~~the treatment of OPC,~~ **MNPR- 101- Zr and MNPR- 101- RIT as well as patients** ~~whom~~

who ~~Validive may~~ have ~~the potential to treat,~~ **advanced soft tissue sarcoma (" ASTS")** is based upon estimates and ~~on~~ various ~~reports~~ **scientific publications** from governments or ~~medical~~ **academic** institutions. These estimates or reports may prove to be incorrect, and new studies may demonstrate or suggest a lower estimated incidence or prevalence of ~~this condition. The number of~~ patients **who might** ~~in the U. S. or elsewhere may turn out to~~ be **eligible or** ~~lower than expected, may not be otherwise~~ amenable to **MNPR** ~~Validive treatment, or treatment~~ **101- Zr, MNPR- 101- RIT, and camsirubicin. Also, eligible or** amenable patients may become increasingly difficult to identify and access **due to many different factors** , **such as increasing competition in** ~~all of which would adversely affect our business prospects and financial condition. In particular,~~ the **radiopharmaceutical space. Moreover, the** ~~treatable~~ **targetable** population for ~~Validive~~ **our MNPR- 101 radiopharmaceutical program and camsirubicin** may further be reduced if our estimates ~~of~~ **or** addressable populations are erroneous or sub- populations of patients within the addressable ~~population~~ **populations** do not ~~derive~~ benefit from ~~Validive~~ **our MNPR- 101 radiopharmaceutical program or camsirubicin** . Risks Related to Our Reliance on Third Parties Corporate, non- profit, and academic collaborators may take actions (including lack of effective actions) to delay, prevent, or undermine the success of our products. Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of product candidates is heavily dependent on us entering into collaborations with corporations, non- profit organizations, academic institutions, licensors, licensees, and other parties. There can be no assurance that we will be successful in establishing such collaborations. Current and future collaborations are and may be terminable at the sole discretion of the collaborator. The activities of any collaborator will not be within our direct control and may not be in our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all; that we will derive any revenue, profits, or benefit from such collaborations; or that any collaborator will not compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake development and commercialization of our proposed products, and may not be able to develop and commercialize such products effectively, if at all. In addition, a lack of development and commercialization collaborations may lead to significant delays in introducing proposed products into certain markets and / or reduced sales of proposed products in such markets. Furthermore, current and future collaborators may act deliberately or inadvertently in ways detrimental to our interests. The termination of third- party licenses could adversely affect our rights to important compounds or technologies ~~. We have exercised our option to license Validive; as such, Onxeo has the ability to terminate the license if we breach our obligations under the license agreement. A termination of the license agreement might force us to cease developing and / or selling Validive, if it gets to market~~ . We rely on certain rights to MNPR- 101 that we have secured through a non- exclusive license agreement with XOMA. XOMA, as licensor, has the ability to terminate the license if we breach our obligations under the license agreement and do not remedy any such breach within a set time after receiving written notice of such breach from XOMA. A termination of the license agreement might force us to cease developing and / or selling MNPR- 101- Zr or MNPR- 101 RIT, if ~~it~~ **either** gets to market. ~~40Data~~ -- **Data** provided by collaborators and other parties upon which we rely have not been independently verified and could turn out to be inaccurate, misleading, or incomplete. We rely on third- party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. We do not independently verify or audit all of such data (including possibly material portions thereof). As a result, such data may be inaccurate, misleading, or incomplete. In certain cases, we may need to rely on a single supplier for a particular manufacturing material or service, and any interruption in or termination of service by such supplier could delay or disrupt the commercialization of our products. We rely on third- party suppliers for the materials used to manufacture our compounds. Some of these materials may at times only be available from one supplier. Any interruption in or termination of service by such single source suppliers could result in a delay or disruption in manufacturing until we locate an alternative source of supply. There can be no assurance that we would be successful in locating an alternative source of supply or in negotiating acceptable terms with such prospective supplier. ~~Our Validive manufacturer is in the United Kingdom (" UK "), and it is unknown in the long- term how they will be impacted by Brexit; however, if they are negatively impacted, this could increase our manufacturing costs, delivery schedules, and adversely impact our financial condition. The UK left the European Union (" EU ") on January 31, 2020, which is commonly referred to as " Brexit. " The full long- term impact of Brexit, however, remains uncertain. Our Validive manufacturer may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. The tax consequences of the UK' s withdrawal from the EU are uncertain as well. If Brexit has a detrimental effect on our Validive manufacturer, it could, in turn, adversely impact our manufacturing costs and financial condition.~~ We rely on a limited number of contracted manufacturing plants. If we need to enlist new contract manufacturers, it will delay our **MNPR- 101 radiopharmaceutical program and our** camsirubicin ~~clinical~~ program and may increase ~~our~~ **the** ~~cost~~ **costs** ~~for~~ **of** our ~~Phase 1b and future camsirubicin~~ clinical trials. Our contracted camsirubicin active pharmaceutical ingredient manufacturing plant ~~and~~ **as well as** our contracted raw materials manufacturing plant are in countries in Asia and Europe, either of which may be affected by imposed tariffs and regional geopolitical factors outside of their control, including the Russia- Ukraine war **and Israel- Hamas war** , which may affect the supply of camsirubicin active pharmaceutical ingredient and raw materials. If we need to enlist new contract manufacturers, it will delay our camsirubicin clinical program and may increase our cost for our Phase 1b and future camsirubicin **clinical trials. Our contracted MNPR- 101- Zr manufacturing plant as well as our raw material supplier are currently located in the U. S., but the Russia- Ukraine war and Israel- Hamas war may adversely affect the sourcing of radioisotopes and timely supply of MNPR- 101- Zr to clinical sites. If we need to enlist new contract manufacturers, it will delay our MNPR- 101- Zr clinical program and may increase our cost for the currently ongoing or future** clinical trials. We rely on third parties to conduct our non- clinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our current product candidates or any future products, on a timely and efficient basis or at all, and our financial condition will be adversely affected. We do not have the capacity to independently conduct non- clinical studies and clinical

trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as contract research organizations or clinical research organizations, to conduct non- clinical studies and clinical trials on our product candidates. The third parties with whom we contract for execution of our non- clinical studies and clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on third parties to conduct our non- clinical studies and clinical trials, we remain responsible for ensuring that each of our non- clinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA, **TGA,** EMA and other foreign regulatory authorities require us to comply with regulations and standards, including some regulations commonly referred to as good clinical practices (" GCPs "), for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. ~~41In~~ **In** addition, the execution of non- clinical studies and clinical trials, and the subsequent compilation and analyses of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. Under certain circumstances, these third parties may be able to terminate their agreements with us upon short notice. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain, on a timely and efficient basis or at all, regulatory approval for or to commercialize the product candidate being tested in such trials, and as a result, our financial condition will be adversely affected. Risks Related to Commercialization of Our Product Candidates We have no experience as a company in commercializing any product. If we fail to obtain commercial expertise, upon product approval by regulatory agencies, our product launch and revenues could be delayed. As a company, we have never obtained regulatory approval for, or commercialized, any product. Accordingly, we have not yet begun to build out any sales or marketing or distribution capabilities. If we are unable to establish, or contract for, effective sales and marketing and distribution capabilities, or if we are unable to enter into agreements with third parties to commercialize our product candidates on favorable terms or on any reasonable terms at all, we may not be able to effectively generate product revenues once our product candidates are approved for marketing. If we fail to obtain commercial expertise or capabilities, upon drug approval, our product launch and subsequent revenues could be delayed and / or fail to reach their commercial potential. Our product development efforts are at an early stage. We have not yet undertaken any marketing efforts, and there can be no assurance that future anticipated market testing and analyses will validate our marketing strategy. We may need to modify the products, or we may not be successful in either developing or marketing those products. As a company, we have not completed the development or clinical trials of any product candidates and, accordingly, have not yet begun to market or generate revenue from the commercialization of any products. Obtaining approvals of these product candidates will require substantial additional research and development as well as costly clinical trials. There can be no assurance that we will successfully complete development of our product candidates or successfully market them. We may encounter problems and delays relating to research and development, regulatory approval, intellectual property rights of product candidates, or other factors. There can be no assurance that our development programs will be successful, that our product candidates will prove to be safe and effective in or after clinical trials, that the necessary regulatory approvals for any product candidates will be obtained, or, even if obtained, will be as broad as sought or will be maintained for any period thereafter, that patents will issue on our patent applications, that any intellectual property protections we secure will be adequate, or that our collaboration arrangements will not diminish the value of our intellectual property through licensing or other arrangements. Furthermore, there can be no assurance that any product we might market will be received favorably by customers (whether physicians, payers, patients, or all three), adequately reimbursed by third- party payers, or that competitive products will not perform better and / or be marketed more successfully. Additionally, there can be no assurances that any future market testing and analyses will validate our marketing strategies. We may need to seek to modify the product labels through additional studies in order to be able to market them successfully to reach their commercial potential. If we are unable to establish relationships with licensees or collaborators to carry out sales, marketing, and distribution functions or to create effective marketing, sales, and distribution capabilities, we will be unable to market our products successfully. Our business strategy may include out- licensing product candidates to or collaborating with larger firms with experience in marketing and selling pharmaceutical products. There can be no assurance that we will successfully be able to establish marketing, sales, or distribution relationships with any third- party, that such relationships, if established, will be successful, or that we will be successful in gaining market acceptance for any products we might develop. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues per unit sold are expected to be lower than if we marketed, sold, and distributed our products directly, and any revenues we receive will depend upon the efforts of such third parties. ~~42If~~ **If** we are unable to establish such third- party marketing and sales relationships, or choose not to do so, we would have to establish in- house marketing and sales capabilities. We have no experience in marketing or selling oncology pharmaceutical products, and currently have no marketing, sales, or distribution infrastructure and no experience developing or managing such infrastructure for an oncology related product. To market any products directly, we would have to establish a marketing, sales, and distribution force that has technical expertise and could support a distribution capability. Competition in the biopharmaceutical industry for technically proficient marketing, sales, and distribution personnel is intense and attracting and retaining such personnel may significantly increase our costs.

There can be no assurance that we will be able to establish internal marketing, sales, or distribution capabilities or that these capabilities will be sufficient to meet our needs. Commercial success of our product candidates will depend on the acceptance of these products by physicians, payers, and patients. Any product candidate that we may develop may not gain market acceptance among physicians, payers and patients. Market acceptance of and demand for any product that we may develop will depend on many factors, including without limitation: ● Comparative superiority of the efficacy and safety in the treatment of the disease indication compared to alternative treatments; ● Less incidence, less prevalence and more severity of adverse side effects; ● Potential advantages over alternative treatments; ● Cost effectiveness; ● Convenience and ease of administration, stability and shelf life, for distributor, physician and patient; ● Sufficient third- party coverage and / or reimbursement; ● Strength of sales, marketing and distribution support; and ● Our ability to provide acceptable and compelling evidence of safety and efficacy. If any product candidate developed by us receives regulatory approval but does not achieve an adequate level of market acceptance by physicians, payers, and patients, we may generate insufficient, little, or no product revenue to earn appropriate returns on the investment of product development costs and may not become profitable at sufficient product sales volumes to earn sustainable profitability. Our products may not be accepted for reimbursement or adequately reimbursed by third- party payers. The successful commercialization of any products we might develop will depend substantially on whether the costs of our products and related treatments are reimbursed at acceptable levels by government authorities, private healthcare insurers, and other third- party payers, such as health maintenance organizations. Reimbursement rates may vary, depending upon the third- party payer, the type of insurance plan, and other similar or dissimilar factors. If our products do not achieve adequate reimbursement, then the number of physician prescriptions of our products may not be sufficient to make our products profitable, and to earn a sufficient profit to earn a reasonable return on our investment and a provide a cash flow to finance future investments on the next generation of products and investments in new technological platforms. Comparative effectiveness research demonstrating benefits of a competitor' s product could adversely affect the sales of our product candidates. If third- party payers do not consider our products to be cost- effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis sufficient for our Company to remain competitive and thrive. ~~43Adequate~~ -- **Adequate** third- party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in the product development of that product. In addition, in the U. S. there is a growing emphasis on comparative effectiveness research, both by private payers and by government agencies. To the extent other drugs or therapies are found to be more effective than our products, payers may elect to cover such therapies in lieu of our products or reimburse our products at a lower rate. The effects of economic and political pressure to lower pharmaceutical prices are a major threat to the economic viability of new research-based pharmaceutical products, and any significant decrease in drug prices could materially and adversely affect our prospects. Emphasis on managed care and government price controls in the U. S. has increased and we expect this will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Any development along these lines could materially and adversely affect our prospects. We are unable to predict what political, legislative or regulatory changes relating to the healthcare industry, including without limitation any changes affecting governmental and / or private or third-party coverage and reimbursement, may be enacted in the future, or what effect such legislative or regulatory changes would have on our business. However, if governmental price management does not provide for the very high price of pharmaceutical research, it could create very demanding challenges for our industry and our prospects or require breakthroughs in research productivity, of which there can be no assurance. If we obtain FDA approval for any of our product candidates, we will be subject to various federal and state fraud and abuse laws; these laws may impact, among other things, our proposed sales, marketing and education programs. Fraud and abuse laws are expected to increase in breadth and in detail, which will likely increase our operating costs and the complexity of our programs to ensure compliance with such enhanced laws. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the U. S., our operations may be directly, or indirectly through our customers, distributors, or other business partners, subject to various federal and state fraud and abuse laws, including, without limitation, anti- kickback statutes and false claims statutes which may increase our operating costs. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct business. If our operations are found to be in violation of any of the federal and state fraud and abuse laws or any other governmental regulations that apply to us, we may be subject to criminal actions and significant civil monetary penalties, which would adversely affect our ability to operate our business and our results of operations. If our operations are found to be in violation, even inadvertently, of any of the federal and state fraud and abuse laws, including, without limitation, anti- kickback statutes and false claims statutes or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our product candidates are ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post- marketing requirements, including safety surveillance, anti- fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. ~~44Negotiated~~ -- **Negotiated** prices for our products covered by a Part D prescription drug plan and other government programs will be lower than the prices we might otherwise obtain. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval; however, any negotiated prices for our products covered by a Part D prescription drug plan and other government programs will be lower than the prices we might otherwise obtain. We anticipate that the number and type of

products that will be subject to federal pricing will increase substantially over time. There may be rules to demand that the government and medical institutions, which are in part supported by government funding, will be granted access to medicines at the same highly favorable prices given to the governmental direct medical care programs. Risks Related to Our Intellectual Property If we and our third- party licensors do not obtain and preserve protection for our respective intellectual property rights, our competitors may be able to take advantage of our (and our licensors') development efforts to develop competing drugs. Our commercial success will depend in part on obtaining patent protection for any products and other technologies we might develop, and successfully defending any patents we obtain against third- party challenges. ~~We have licensed all intellectual property related to Validive from Onxeo S. A., a French public company.~~ See " Business – License, Development and Collaboration Agreements ". The assignment and transfer of the camsirubicin (formerly GPX- 150) patent portfolio from TacticGem, LLC (" TacticGem ") to us has been completed. We filed and have been granted in the U. S. and various countries around the world patents for antibodies that target uPAR for our MNPR- 101 program. We have also been granted in the U. S. and various countries around the world patents to a specific sequence of amino acids on uPAR, to which our MNPR- 101 antibody binds. We are currently prosecuting this patent in other countries around the world to further protect MNPR- 101. We also have jointly applied for patents with our collaborator, NorthStar, for MNPR- 101- Zr and MNPR- 101 **-** RIT conjugates. The patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in obtaining and defending patents. See " Business- Intellectual Property Portfolio and Exclusivity ". These risks and uncertainties include without limitation the following: ● Patents that may be issued or licensed may be challenged, invalidated, or circumvented; or may not provide any competitive advantage for other reasons. ● Our licensors may terminate or breach our existing or future license agreements, thereby reducing or preventing our ability to exclude competition; termination of such license agreements may also subject us to risk of patent infringement of patents to which we no longer have a license. ● Our competitors, many of which have substantially greater resources than us and have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the U. S. or in international markets. ● As a matter of public policy regarding worldwide health concerns, there may be significant pressure on the U. S. government and other international governmental bodies to limit the scope of domestic and international patent protection for cancer treatments that prove successful. ● Countries other than the U. S. may have less restrictive patent laws than those upheld by the U. S. courts; therefore, non- U. S. competitors could exploit these laws to create, develop, and market competing products. In some countries, the legal compliance with pharmaceutical patents, patent applications and other intellectual property regulations is very weak or actively evaded in some cases with government aid. In addition, the U. S. Patent and Trademark Office (" USPTO ") and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and / or biotechnology- related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting their scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the scope of the patents may be substantially narrower than anticipated. If we permit our patents to lapse or expire, we will not be protected and will have less of a competitive advantage. The value of our products may be greatly reduced if this occurs. Our patents expire at different times and are subject to the laws of multiple countries. Some of our patents are currently near expiration and we may pursue patent term extensions for these where appropriate **or permit them to lapse** . See " Business- Intellectual Property Portfolio and Exclusivity ". ~~45In~~ **In** addition to patents, we also rely on trade secrets and proprietary know- how. While we take measures to protect this information by entering into confidentiality and invention agreements with our employees, consultants and collaborators, we cannot provide any assurances that these agreements will be fully enforceable and will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure if they are not fully enforceable or are breached, that any remedy for a breach will adequately compensate us, that these agreements will achieve their intended aims, or that our trade secrets will not otherwise become known or be independently discovered by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U. S., are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed, and the value of the trade secrets may be greatly reduced. The patent protection we obtain and preserve for our product candidates may not be sufficient to provide us with any material competitive advantage. We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products or future products ~~. When looking at our Validive patents' ability to block competition, the protection offered by our patents may be, to some extent, more limited than the protection provided by patents claiming the composition of matter of entirely new chemical structures previously unknown~~ . If a competitor were able to successfully design around any method of use and formulation patents we may have now or in the future, it is highly likely that our business and competitive advantage would be adversely affected. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. If this occurs, our competitive position, business, financial condition, results of operations, and prospects would be materially harmed. Patents have a limited lifespan. In the U. S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are

obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects would be materially harmed.

~~46Intellectual~~ -- **Intellectual** property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights. The biopharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation and USPTO post-grant proceedings to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the USPTO to determine the priority and patentability of inventions. The defense and prosecution of intellectual property suits, USPTO proceedings, and related legal and administrative proceedings are costly and time- consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know- how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or USPTO post- grant and interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Even if a given patent or intellectual property dispute were settled through licensing or similar arrangements, our costs associated with such arrangements may be substantial and could include the payment by us of large, fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all. Even where we have meritorious claims or defenses, the costs of litigation may prevent us from pursuing these claims or defenses and / or may require extensive financial and personnel resources to pursue these claims or defenses. In addition, it is possible there may be defects of form in our current and future patents that could result in our inability to defend the intended claims. Intellectual property disputes arising from the aforementioned factors, or other factors, may materially harm our business. We may not be able to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U. S. Companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market ~~Validive~~ **our current** or any future ~~products~~ **product candidates**. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U. S. and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our products and technology. Changes to the patent law in the U. S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal diligence and complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the U. S. has recently enacted and is currently implementing wide ranging patent reform legislation. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U. S. Congress, the federal courts and the USPTO, as well as other jurisdictions around the world, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing

patents and patents that we might obtain in the future. ~~47Obtaining~~ -- **Obtaining** and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance due to issues beyond our control, can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. If we fail to comply with our obligations under any license, collaboration or other intellectual property- related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or drug candidates or we could lose certain rights to grant sublicenses. Any license, collaboration or other intellectual property- related agreements impose, and any future license, collaboration or other intellectual property- related agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license. In spite of our best efforts, any of our future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technologies covered by these license agreements. Any license agreements we enter into may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may seek to obtain licenses from licensors in the future, however, we may be unable to obtain any such licenses at a reasonable cost or on reasonable terms, if at all. In addition, if any of our future licensors terminate any such license agreements, such license termination could result in our inability to develop, manufacture and sell products that are covered by the licensed technology or could enable a competitor to gain access to the licensed technology. Any of these events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and ability to achieve profitability. Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce and defend patents we may in- license, or lose rights to licensed patents or patent applications, our license rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or drug candidates that is the subject of such licensed rights could be materially adversely affected. In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor' s intellectual property rights and the amount of any damages or future royalty obligations that would result, if any such claims were successful, would depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, due to such obligations, we may be unable to achieve or maintain profitability. ~~48Third~~ -- **Third** parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business. Our commercial success depends, in part, upon our ability or the ability of any of our future collaborators to develop, manufacture, market and sell our current or any future drug candidates and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary and intellectual property rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We or any of our future licensors or strategic partners, may be party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current or any potential future drug candidates and technologies, including derivation, reexamination, inter partes review, post- grant review or interference proceedings before the USPTO and similar proceedings in jurisdictions outside of the U. S. such as opposition proceedings. If we or our licensors or strategic partners are unsuccessful in any interference proceedings or other priority or validity disputes (including through any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents or our patent claims may be narrowed, invalidated, or held unenforceable. In some instances, we may be required to indemnify our licensors or strategic partners for the costs associated with any such adversarial proceedings or litigation. Third parties may also assert infringement, misappropriation or other claims against us, our licensors or our strategic partners based on existing patents or patents that may be granted in the future, as well as other intellectual property rights, regardless of their merit. There is a risk that third parties may choose to engage in litigation or other adversarial proceedings with us, our licensors or our strategic partners to enforce or otherwise assert their patent rights or other intellectual property rights. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third- party patents and other intellectual property rights are valid, enforceable and infringed, which could have a material adverse impact on our ability to utilize our developed technologies or to commercialize our current or any future drug candidates deemed to be infringing. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity by presenting clear and convincing evidence of invalidity. There is no assurance that a court of competent jurisdiction, even if presented with evidence

we believe to be clear and convincing, would invalidate the claims of any such U. S. patent. Further, we cannot guarantee that we will be able to successfully settle or otherwise resolve such adversarial proceedings or litigation. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time- consuming litigation and may be prevented from or experience substantial delays in marketing our drug candidates. If we or any of our licensors or strategic partners are found to infringe, misappropriate or violate a third- party patent or other intellectual property rights, we could be required to pay damages, including treble damages and attorney' s fees, if we are found to have willfully infringed. In addition, we, or any of our licensors or strategic partners may choose to seek, or be required to seek, a license from a third- party, which may not be available on commercially reasonable terms, if at all. Even if a license can be obtained on commercially reasonable terms, the rights may be non- exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us, and we could be required to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease utilizing, developing, manufacturing and commercializing our developed technologies or drug candidates deemed to be infringing. We may be forced to redesign current or future technologies or products. Any of the foregoing could have a material adverse effect on our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we or our licensors or strategic partners may find it necessary to pursue claims or to initiate lawsuits to protect or enforce our patent or other intellectual property rights. If we or our licensors or strategic partners were to initiate legal proceedings against a third- party to enforce a patent covering one of our drug candidates or our developed technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U. S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, claiming patent- ineligible subject matter, lack of novelty, indefiniteness, lack of written description, non- enablement, anticipation or obviousness. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome of such invalidity and unenforceability claims is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensors or strategic partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection for one or more of our drug candidates. The narrowing or loss of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technologies and products. All of these events could have a material adverse effect on our business, financial condition, results of operations and prospects. Patent and other intellectual property rights also will not protect our drug candidates and technologies if competitors or third parties design around such drug candidates and technologies without legally infringing, misappropriating or violating our patent or other intellectual property rights. ~~49The~~ -- **The** cost to us in defending or initiating any litigation or other proceedings relating to our patent or other intellectual property rights, even if resolved in our favor, could be substantial, and any litigation or other proceedings would divert our management' s attention and distract our personnel from their normal responsibilities. Such litigation or proceedings could materially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to more effectively sustain the costs of complex patent litigation because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and materially limit our ability to continue our operations. Furthermore, because of the substantial amount of discovery required in connection with certain such proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, such announcements could have a material adverse effect on the price of our common stock. Intellectual property rights of third parties could adversely affect our ability to commercialize our current or future technologies or drug candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current or future technologies or drug candidates, which may not be available on commercially reasonable terms, or at all. There are numerous companies that have pending patent applications and issued patents broadly covering immune- therapies generally or covering small molecules directed against the same targets as, or targets similar to, those we are pursuing. Our competitive position may materially suffer if patents issued to third parties or other third- party intellectual property rights cover our current or future technologies, drug candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current or future technologies or drug candidates unless we successfully pursue litigation to nullify or invalidate the third- party intellectual property rights concerned or enter into a license agreement with the intellectual property rights holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our current or future technologies or drug candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current or future technologies or drug candidates. Should such an infringement claim be successfully brought, we may be required to pay substantial damages or be forced to abandon our current or future technologies or drug candidates or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all. Third- party intellectual property rights holders may also actively bring infringement, misappropriation or other claims alleging violations of intellectual property rights against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time- consuming litigation and may be prevented from, or experience substantial delays in, marketing our drug candidates. If we fail in

any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future technologies or drug candidates that are held to be infringing, misappropriating or otherwise violating third- party intellectual property rights. We might, if possible, also be forced to redesign current or future technologies or drug candidates so that we no longer infringe, misappropriate or violate the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on our financial condition and results of operations. Risks Related to Our Business Operations and Industry We have a limited operating history. To date, we have engaged exclusively in acquiring pharmaceutical product candidates, licensing rights to product candidates, entering into collaboration agreements with respect to key services or technologies for our drug product development, and ~~commenced~~ **conducted** clinical trials, but have not yet ~~completed any clinical trials,~~ received any governmental approvals, brought any product to market, manufactured products in commercial quantities or sold any pharmaceutical products. As a company we have limited experience in negotiating, establishing, and maintaining strategic relationships, conducting clinical trials, and managing the regulatory approval process, all of which will be necessary if we are to be successful. Our lack of experience in these critical areas makes it difficult for a prospective investor to evaluate our abilities and increases the risk that we will fail to successfully execute our strategies. ~~50Furthermore~~ -- **Furthermore** , if our business grows rapidly, our operational, managerial, legal, and financial resources will be strained. Our development will require continued improvement and expansion of our management team and our operational, managerial, legal, and financial systems and controls. In the normal course of business, we have evaluated and expect to evaluate potential acquisitions and / or licenses of patents, compounds, and technologies that our management believes could complement or expand our business. In the event that we identify an acquisition or license candidate we find attractive, there is no assurance that we will be successful in negotiating an agreement to acquire or license, or in financing or profitably exploiting, such patents, compounds, or technologies. Furthermore, such an acquisition or license could divert management time and resources away from other activities that would further our current business development. If we lose key management leadership, and / or scientific personnel, and if we cannot recruit qualified employees, managers, directors, officers, or other significant personnel, it is highly likely that we will experience program delays and increases in compensation costs, and our business will be materially disrupted. Our future success is highly dependent on the continued service of principal members of our management, leadership, and scientific personnel, who are able to terminate their employment with us at any time and may be able to compete with us. The loss of any of our key management, leadership, or scientific personnel including, in particular, Christopher M. Starr, our Executive Chairman of the Board of Directors (referred to as the " Board "), and Chandler D. Robinson, our President and CEO, could materially disrupt our business and materially delay or prevent the successful product development and commercialization of our product candidates. We have an employment agreement with Dr. Robinson which has no term but is for at- will employment, meaning the executive has the ability to terminate his employment at any time. We have a consulting agreement with Dr. Starr that is terminable with 30- days' notice by Dr. Starr or us. Our future success will also depend on our continuing ability to identify, hire, and retain highly skilled personnel for all areas of the organization. Competition in the biopharmaceutical industry for scientifically and technically qualified personnel is intense, and we may be unsuccessful in identifying, hiring, and retaining qualified personnel. Our continued requirement to identify, hire, and retain highly competent personnel may cause our compensation costs to increase materially. We incur costs as a result of operating as a public company, and our management is required to devote substantial time to investor relations, information and communication to the public, and related compliance initiatives and corporate governance practices. As a public company, and particularly after we are no longer an emerging growth company **after 2024** , we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our Board. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. ~~51Despite~~ -- **Despite** ongoing compliance training and periodic education, our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in delays or terminations of our development programs and adversely affect our business. Although we regularly train our employees on compliance and we are aware of no misconduct or improper activities to date, we are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to: comply with FDA regulations; provide accurate information to the FDA; comply with manufacturing standards; comply with federal and state healthcare fraud and abuse laws and regulations; report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and consultant misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always

possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Such actions could adversely affect our business including delaying or terminating one or more of our development programs. We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors. We are an emerging growth company. Under the Jumpstart Our Business Startups Act of 2012 (the " JOBS Act "), emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies. For as long as we continue to be an emerging growth company, we ~~also~~ intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements (auditor discussion and analysis). If we do take advantage of these exemptions, the information that we provide stockholders will be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If investors find our common stock less attractive as a result of our status as an emerging growth company, there may be less liquidity for our common stock and our stock price may be more volatile. We will remain an emerging growth company until the earliest of (1) the last day of the year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $ 1. 235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non- affiliates exceeds $ 700 million as of the prior June 30th, and (2) the date on which we have issued more than $ 1. 0 billion in non- convertible debt securities during the prior three- year period. We anticipate this will be December 31, 2024. **Even after we no longer qualify as an emerging growth company, we may remain a " smaller reporting company " and " non- accelerated filer " and rely on certain reduced disclosure obligations and / or exemptions available to such companies.** Competition and technological change may make our product candidates less competitive or obsolete. The biopharmaceutical industry is subject to rapid technological change. We have many potential competitors, including major drug and chemical companies, specialized biopharmaceutical firms, universities and other research institutions. These companies, firms, and other institutions may develop products that are more effective than our product candidates or that would make our product candidates less competitive or obsolete. Many of these companies, firms, and other institutions have greater financial resources than us and may be better able to withstand and respond to adverse market conditions within the biopharmaceutical industry, including without limitation the lengthy product development and regulatory approval processes for product candidates. ~~52We~~ **We** face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe we have significant competitive advantages with our expertise in small molecules and biologics, and rare disease clinical development, along with a strong intellectual property portfolio, we currently face and will continue to face competition for our drug development programs from companies that ~~target SOM,~~ are developing doxorubicin analogs / ~~replacement~~ **replacements** , or are targeting uPAR. The competition is likely to come from multiple sources, including larger pharmaceutical companies, biotechnology companies and academia. Accordingly, our competitors may have more resources and be more successful than us in obtaining approval for treatments and achieving widespread market acceptance. For any products that we may ultimately commercialize, not only will we compete with any existing therapies and those therapies currently in development, we will have to compete with new therapies that may become available in the future. We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases, and out- licensing or in- licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction will require us to incur non- recurring or other charges, may increase our near- and long- term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including: ● exposure to unknown technologies, product candidates, medical conditions and indications, product manufacturing challenges and uncertainties, and other unknown factors of potential high risk; ● disruption of our business and diversion of our management' s time and attention in order to develop acquired products, product candidates or technologies; ● incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions; ● higher- than- expected acquisition and integration costs; ● write-downs of assets, goodwill or impairment charges; ● increased amortization expenses; ● difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; ● impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and ● inability to retain key employees of any acquired businesses or for our current business based on changed circumstances. Accordingly, although there

can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, results of operations, financial condition and prospects. ~~53Our~~ -- **Our** business and operations are vulnerable to computer system failures, cyber- attacks or deficiencies in our ~~cyber- security~~ **cybersecurity** , which could increase our expenses, divert the attention of our management and key personnel away from our business operations and adversely affect our results of operations. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from: computer viruses; malware; natural disasters; terrorism; war; telecommunication and electrical failures; cyber- attacks or cyber- intrusions over the Internet; attachments to emails; persons inside our organization; or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, and damage to our reputation, and the further development of our product candidates could be delayed. We could be forced to expend significant resources in response to a cyber security breach, including repairing system damage, increasing cyber security protection costs by deploying additional personnel and protection technologies, paying regulatory fines and resolving legal claims and regulatory actions, all of which would increase our expenses, divert the attention of our management and key personnel away from our business operations and adversely affect our results of operations. Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. We and our current and any of our future collaborators may be subject to federal, state and foreign data protection laws and regulations (i. e., laws and regulations that address privacy and data security). In the U. S., numerous federal and state laws and regulations, including federal health information privacy laws (e. g., the Health Insurance Portability and Accountability Act (" HIPAA "), as amended by the Health Information Technology for Economic and Clinical Health Act (" HITECH ")), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. International data protection laws, including Regulation 2016 / 679, known as the General Data Protection Regulation (" GDPR ") may also apply to health- related and other personal information obtained outside of the U. S. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the EU, as well as potential fines for non- compliant companies of up to the greater of € 20 million or 4 % of annual global revenue. The regulation imposes numerous new requirements for the collection, use, storage and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e. g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross- border data transfers. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. **In Australia, they have enacted robust** ~~Further Brexit has created uncertainty with regard to~~ data protection ~~regulation~~ **regulations** ~~in~~ **to safeguard personal information of its citizens. These laws include the Federal Privacy Act of 1988 and Privacy Legislation Amendment Act of 2022. These laws also specifically address data protection measures such data residency requirements, requirements for handling personal health records and data subject rights that detail specific rights Australian citizens have on the collection and use of** ~~the~~ **their** ~~United Kingdom~~ **personal data** . In ~~particular, it is unclear how data transfers to and from the United Kingdom will be regulated. 54In~~ addition, California ~~recently~~ enacted the California Consumer Privacy Act (" CCPA "), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA ~~will require~~ **requires** covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt- out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and **certain amendments went into effect in** ~~the California Attorney General may bring enforcement actions for violations beginning July 1, 2020~~ **2023 . Other states have adopted similar laws** . The CCPA ~~was amended on September 23~~ , ~~2018,~~ and ~~it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the~~ **other** ~~CCPA~~ **state privacy laws,** may impact our business activities and ~~exemplifies~~ **exemplify** the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Compliance with U. S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in

certain jurisdictions. Failure to comply with U. S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. If we, our contract research organizations (" CROs ") or our IT vendors experience security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of personal data, we may face costs, significant liabilities, harm to our brand and business disruption. In connection with our drug research and development efforts, we or our CROs may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. Although we have extensive measures in place to prevent the sharing and loss of patient data in our clinical trial processes associated with our developed technologies and drug candidates, any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e. g., state breach notification laws), federal (e. g., HIPAA, as amended by HITECH), and international laws (e. g., the GDPR). Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business. We may also rely on third- party IT vendors to host or otherwise process some of our data and that of users, and any failure by such IT vendor to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected. Our research and development and drug candidates and future commercial manufacturing may involve the use of hazardous materials and various chemicals. We currently do not maintain a research laboratory, but we engage third- party research organizations and manufacturers to conduct our preclinical studies, clinical trials and manufacturing. These third- party laboratories and manufacturers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We must rely on the third parties' procedures for storing, handling and disposing of these materials in their facilities to comply with the relevant guidelines of the states in which they operate and the Occupational Safety and Health Administration of the U. S. Department of Labor. Although we believe that their safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, this could result in significant delays in our development. We are also subject to numerous environmental, health and workplace safety laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations. We have limited the liability of and indemnified our directors and officers. Although our directors and officers are accountable to us and must exercise good faith, good business judgement, and integrity in handling our affairs, our Second Amended and Restated Certificate of Incorporation (the " Certificate of Incorporation ") and indemnification agreements executed by all of our non- employee directors and officers provides that our non- employee directors and officers will be indemnified to the fullest extent permitted under Delaware law. As a result, our stockholders may have fewer rights against our non- employee directors and officers than they would have absent such provisions in our Certificate of Incorporation and indemnification agreements, and a stockholder' s ability to seek and recover damages for a breach of fiduciary duties may be reduced or restricted. Delaware law allows indemnification of our non- employee directors and officer, if they (a) have acted in good faith, in a manner the non- employee director or officer reasonably believes to be in or not opposed to our best interests, and (b) with respect to any criminal action or proceeding, if the non- employee director or officer had no reasonable cause to believe the conduct was unlawful. ~~55Pursuant~~ -- **Pursuant** to the Certificate of Incorporation and indemnification agreement, each non- employee director and officer who is made a party to a legal proceeding because he or she is or was a non- employee director or officer, is indemnified by us from and against any and all liability, except that we may not indemnify a non- employee director or officer: (a) for any liability incurred in a proceeding in which such person is adjudged liable to Monopar or is subjected to injunctive relief in favor of Monopar; (b) for acts or omissions that involve intentional misconduct or a knowing violation of law, fraud or gross negligence; (c) for unlawful distributions; (d) for any transaction for which such non- employee director or officer received a personal benefit or as otherwise prohibited by or as may be disallowed under Delaware law; or (e) with respect to any dispute or proceeding between us and such non- employee director or officer unless such indemnification has been approved by a disinterested majority of the Board or by a majority in interest of disinterested stockholders. We are required to pay or reimburse attorney' s fees and expenses of a non- employee director or officer seeking indemnification as they are incurred, provided the non- employee director or officer executes an agreement to repay the amount to be paid or reimbursed if there is a final determination by a court of competent jurisdiction that such person is not entitled to indemnification. Future legislation or executive or private sector actions may increase the difficulty and cost for us to commercialize our products and adversely affect the prices obtained for such products. In the U. S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act (the " ACA "), was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U. S. pharmaceutical industry. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. ~~Various portions~~ **If any** of ~~the~~ **these developments** ~~ACA are currently undergoing legal and constitutional challenges in the US Supreme Court; the Trump Administration signed various executive orders and other directives that eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare~~

~~providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The US Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in 2021. The American Rescue Plan Act of 2021 which was recently enacted into law includes provisions which further the ACA, including expansion of marketplace subsidies and credits to reduce or eliminate premiums in the federal exchange for persons with certain income levels and providing subsidies for state exchanges. The implementation of the ACA is ongoing, the law appears likely to~~ continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, **or** ~~and may also~~ increase regulatory burdens and operating costs ~~. Litigation and legislation related to the ACA are likely to continue~~ , **it could adversely impact** ~~with unpredictable and uncertain results. It is unclear whether the ACA will be overturned, repealed, replaced, or~~ **our business** ~~further amended~~ . We cannot predict what ~~affect~~ **effect** further changes to the ACA would have on our business. In addition, government price reporting and payment regulations are complex, and we will be required to continually assess the methods by which we plan to calculate and report any future pricing in accordance with these obligations. Our methodologies for calculations are inherently subjective and may be subject to review and challenge by various government agencies, which may disagree with our interpretation. If the government disagrees with our reported calculations, we may need to restate the previously reported data and could be subject to additional financial and legal liability. Further, the increasing cost of healthcare as a percentage of GDP and the massive and increasing deferred liabilities behind most governmental healthcare programs (such as Medicare and Medicaid and state and local healthcare programs especially for retirement benefits) continue to be an economic challenge which threatens the overall economic health of the U. S. High cost healthcare products and therapies that are early in their life cycle are attractive targets for parties that believe that the cost of healthcare must be better controlled and significantly reduced. Pharmaceutical prices and healthcare reform have been debated and acted upon by legislators for many years. Future legislation or executive or private sector actions related to healthcare reform could materially and adversely affect our business by reducing our ability to generate revenue at prices sufficient to reward for the risks and costs of pharmaceutical development, to raise capital, and to market our products. ~~56There~~ -- **There** is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform and third- party payers will affect the pharmaceutical industry in general and our business in particular. Even if we are able to commercialize any drug candidate, such drug candidate may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, which would harm our business. Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third- party payors, such as government authorities, private healthcare insurers and health maintenance organizations. Patients who are prescribed medications for the treatment of their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private healthcare insurers are critical to new product acceptance. Patients are unlikely to use our future products, if any, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. Cost- containment is a priority in the U. S. healthcare industry and elsewhere. As a result, government authorities and other third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third- party payors also may request additional clinical evidence beyond the data required to obtain marketing approval, requiring a company to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of its products. Commercial third- party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for pharmaceutical products in the U. S. can differ significantly from payor to payor. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval. Additionally, the regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval. Politically divided governmental actions and related political actions outside of government can impact the FDA' s role in the timely and effective review of new pharmaceutical products in the U. S. and our business may be adversely impacted. ~~A relevant example~~ **In recent years, there has been significant political conflict around budgeting and governmental funding** of ~~dysfunctional~~ **operations in the U. S. Government. Shutdowns or threats to** government ~~was the 35- day government shutdown~~ **shutdowns** ~~that ended February 15~~ **are recurring events. In the past** , ~~2019~~ **these events have** , ~~which~~ limited the FDA to activities necessary to address imminent threats to human life and to activities funded by carry- over user fees. Future government shutdowns or other activities which limit the financial resources available to the FDA (and in particular to the Center for Drug Evaluation and Research) will delay the processing of new product drug development submissions, reviews, and approvals and other required regulatory actions. Such delays will adversely impact our business and

financial condition. ~~57Effective~~ -- **Effective** collaboration with the FDA ~~' s Center for Drug Evaluation and Research (" CDER ") ~~for the approval of drug candidates is a highly demanding process which can result in increased time and expense to gain approvals ~~. Our lead drug development program, Validive, will be reviewed by CDER. Efficient and professional collaboration with the FDA' s CDER is essential for the timely clinical testing, test evaluations, analysis and approval of our drug candidates. CDER has an outstanding record of drug approvals and substantial funds to operate a highly professional organization but is also very demanding as to the quality of clinical research and applications for marketing approvals for drug candidates~~ . Our Company has in- house expertise and experience in the management of drug approvals. Qualified consultants and drug research organizations are also available to aid in our drug approval process; however, there is a meaningful risk that discussions and interactions inherent in the drug approval process and future developments or new improvements will result in delays, added expenses and new scientific / medical requirements which will cause adverse financial results and will likely impact the price of the Company' s stock. Future tax reform measures may negatively impact our financial position. Tax reform measures are unpredictable and can change as the U. S. Congress and executive leadership changes. For example, on December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law that significantly revised the Internal Revenue Code of 1986, as amended (the " Code "). It is difficult to predict what future tax reform measures, if any, could be implemented and the extent to which they will impact our financial condition and our business. Foreign currency exchange rates may adversely affect our consolidated financial statements. Sales and purchases in currencies other than the U. S. Dollar expose us to fluctuations in foreign currencies relative to the U. S. Dollar and may adversely affect our consolidated financial statements. Increased strength of the U. S. Dollar increases the effective price of our future drug products sold in U. S. Dollars into other countries, which may require us to lower our prices or adversely affect sales to the extent we do not increase local currency prices. Decreased strength of the U. S. Dollar could adversely affect the cost of materials, products and services we purchase overseas. Sales and expenses of our non- U. S. businesses are also translated into U. S. Dollars for reporting purposes and the strengthening or weakening of the U. S. Dollar could result in unfavorable foreign currency translation and transaction effects. In addition, certain of our businesses may in the future invoice customers in a currency other than the business' functional currency, and movements in the invoiced currency relative to the functional currency could also result in unfavorable foreign currency translation and transaction effects. We also face exchange rate risk from our investments in subsidiaries owned and operated in foreign countries. Our anticipated operating expenses and capital expenditures over the next year are based upon our management' s estimates of possible future events. Actual amounts and the cost of new conditions could differ materially from those estimated by our management. Development of pharmaceuticals and cancer drugs is extremely risky and unpredictable. We have estimated operating expenses and capital expenditures over the next year based on certain assumptions. Any change in the assumptions could cause the actual results to vary substantially from the anticipated expenses and expenditures and could result in material differences in actual versus forecasted expenses or expenditures. Furthermore, all of the factors are subject to the effect of unforeseeable future events. The estimates of capital expenditures and operating expenses represent forward- looking statements within the meaning of the federal securities laws. Prospective investors are cautioned that any such forward- looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward- looking statements as a result of various factors, including the risk factors set forth under this " Risk Factors " section in this Annual Report on Form 10- K. The financial and operational projections that we may make from time to time are subject to inherent risks. The projections that we provide herein or our management may provide from time to time (including, but not limited to, our success in raising strategic and substantial financial resources, the cost and timing of our clinical trials, clinical and regulatory timelines, production and supply matters, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by our management, including assumptions with respect to our specific as well as general business, regulatory, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There may be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in this Annual Report on Form 10- K should not be regarded as an indication that our management considered or consider the projections to be a guaranteed prediction of future events, and the projections should not be relied upon as such. See " Cautionary Statement Concerning Forward- Looking Statements. " ~~58Our~~ -- **Our** present and potential future international operations may expose us to business, political, operational, and financial risks associated with doing business outside of the U. S. Our business is subject to risks associated with conducting business internationally. Some of our suppliers and clinical research organizations and clinical trial sites are located outside of the U. S. Furthermore, if we or any future collaborator succeeds in developing any products, we anticipate marketing them in the EU, the United Kingdom and other jurisdictions in addition to the U. S. If approved, we or our collaborator may hire sales representatives and conduct physician and patient association outreach activities outside of the U. S. Doing business internationally involves a number of risks, including but not limited to: ● multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses which can vary jurisdictions to jurisdiction with different degrees of review and enforcement; ● failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; ● rejection or qualification of foreign clinical trial data by the competent authorities of other countries; ● additional potentially relevant third- party patent and other intellectual property rights that may be necessary to develop and commercialize our products and drug candidates; ● complexities and difficulties in obtaining, maintaining, enforcing and defending our patent and other intellectual property rights; ● difficulties in staffing and managing foreign operations by a small- scale organization; ● complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; ● limits, as a U. S.- based company, in our ability to penetrate international markets; ● financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the

impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; ● natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions, implementation of tariffs; ● certain expenses including, among others, expenses for travel, translation and insurance; and ● regulatory and compliance risks that relate to anti- corruption compliance and record- keeping that may fall within the purview of the U. S. Foreign Corrupt Practices Act, its accounting provisions or its anti- bribery provisions or provisions of anti- corruption or anti- bribery laws in other countries. Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations. ~~59We~~ **We** are subject to U. S. and foreign anti- corruption and anti- money laundering laws with respect to our operations and non- compliance with such laws can subject us to criminal or civil liability and harm our business. We are subject to the U. S. Foreign Corrupt Practices Act of 1977, as amended (" the FCPA "), the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti- bribery and anti- money laundering laws in countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, third- party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government- affiliated hospitals, universities and other organizations. In addition, we may engage third- party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third- party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities. We have a Code of Business Conduct and Ethics which mandates compliance with the FCPA and other anti- corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third- party intermediaries will comply with this code or such anti- corruption laws. Noncompliance with anti- corruption and anti- money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management' s attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens. Risks Associated with our Common Stock Existing and new investors will experience dilution as a result of future sales or issuances of our common stock and future option exercises under our 2016 Stock Incentive Plan and any amendments to the plan. Our non- employee directors, employees, and certain of our consultants have been and will be issued equity and / or granted options that vest with the passage of time. Up to a total of 5, 100, 000 shares of our common stock may be issued as stock options or restricted stock units under the Amended and Restated Monopar Therapeutics Inc. 2016 Stock Incentive Plan, and stock options for the purchase of up to 2, ~~147~~ **119**, ~~790~~ **001** shares of our common stock have already been granted (1, ~~215~~ **553**, ~~724~~ **867** stock options are exercisable) and are outstanding along with ~~633~~ **410**, ~~042~~ **136** restricted stock units that have been granted to non- employee directors and employees as of March ~~10~~ **8**, ~~2023~~ **2024**. The issuance of such equity upon vesting of restricted stock units and / or the exercise of such options **, and the grant of new equity awards,** will dilute both our existing and our new investors. As of March ~~10~~ **8**, ~~2023~~ **2024**, 189, 346 stock options have been exercised. Our existing and our new investors will also experience substantial dilution resulting from the issuance by us of equity securities in connection with certain transactions, including without limitation, future offering of shares in future fundraising efforts, intellectual property licensing, acquisition, or commercialization arrangements. Holders of the shares of our common stock will have no control of our operations or of decisions on major transactions. Our business and affairs are managed by or under the direction of our Board. Our stockholders are entitled to vote only on actions that require a stockholder vote under federal or state law. Stockholder approval requires the consent and approval of holders of a majority or more of our outstanding stock. Shares of stock do not have cumulative voting rights and therefore, holders of a majority of the shares of our outstanding stock will be able to elect all Board members. TacticGem, LLC (" TacticGem ") owns 7, 166, 667 shares of common stock (~~54~~ **41**. ~~34~~ **06** %). The limited liability company agreement requires TacticGem to pass through votes (including the vote for the election of directors) to its members in proportion to their membership percentages in TacticGem (57. 367 % owned by Tactic Pharma and 42. 633 % owned by Gem). As a result, Tactic Pharma, our initial investor, holds an approximately ~~32~~ **24**. ~~4~~ **51** % beneficial interest in us and together with Gem' s beneficial ownership of approximately ~~23~~ **17**. ~~2~~ **50** %, the two entities control a ~~majority~~ **significant portion** of our stock and will ~~be able to~~ **have substantial influence in the** ~~elect~~ **election of** all Board members and control **of** our affairs. ~~Some of~~ **In addition,** our **Chief** ~~Board members and executive~~ **Executive** ~~officers~~ **Officer** ~~own~~ and ~~control~~ **director, as well as one of our other directors, are associated with** Tactic Pharma. ~~Although~~ **The interim analysis for our Validive Phase 2b / 3 clinical program yielded a** no ~~single person has~~ **- go decision resulting in** a ~~controlling interest in Tactic Pharma, acting together,~~ **reduction of our stock price. If our stock price does not increase before** ~~they~~ **the Nasdaq extended deadline for regaining compliance or if we do not win an appeal for additional time, our business could be adversely impacted. The termination of our Validive clinical trial due to the no- go decision at the end of March 2023 resulted in a decrease in our stock price. The closing bid price of our stock fell below $ 1. 00 for more than 30 consecutive trading days and on August 28, 2023 we received a notice from Nasdaq stating that we** are ~~able~~ **out of compliance with Nasdaq listing standards giving us 180 days** to ~~control Tactic Pharma and~~ **regain compliance. On**

February 27, 2024, we were granted a ~~large voting block of our common~~ **second 180- day period to regain compliance by August 26, 2024. However, there can be no assurance that we will regain compliance. If it is necessary to effect a reverse** stock **split to attempt to cure the bid price deficiency, the impacts on our stock price are uncertain** and ~~together with Gem can elect a majority of~~ **could be adverse. If we do not regain compliance, we would face delisting and it may have serious adverse consequences on our ability to raise funds, which may cause us to delay, restructure** ~~our~~ **or** ~~Board~~ **otherwise reconsider our operations** . ~~60Our~~ -- **Our** failure to meet the **other** continued listing requirements of The Nasdaq Capital Market could result in a de- listing of our common stock. If we fail to satisfy ~~the~~ **other** continued listing requirements of The Nasdaq Capital Market, such as **, but not limited to,** the corporate governance requirements ~~or the minimum closing bid price requirement~~ , the Nasdaq Stock Market (" Nasdaq ") may take steps to de- list our common stock. Such a de- listing or the announcement of such de- listing will have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de- listing, we would take actions to restore our compliance with the Nasdaq listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with the Nasdaq listing requirements. The stock price of our common stock may be volatile or may decline regardless of our operating performance. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time- to- time experienced significant price and volume fluctuations that appear to be unrelated to the operating performance of particular companies. Our common stock has only been trading on the Nasdaq Capital Market since December 19, 2019, and has experienced significant volatility in market prices through March ~~10~~ **8** , ~~2023~~ **2024** , ranging from a low of $ ~~1~~ **0** . ~~39~~ **274** to a high of $ 48. 00 **. From time to time, whether in response to news releases or for uncertain reasons, our stock price has also experienced significant intraday volatility and volume changes** . Our small public float and relatively low and inconsistent trading volumes exacerbate volatility. The market price of our common stock is likely to remain highly volatile and may fluctuate substantially due to many factors, including: ● announcements concerning the progress and success of our clinical trials, our ability to obtain regulatory approval for and commercialize our product candidates, including any requests we receive from the FDA **or TGA** for additional studies or data that result in delays in obtaining regulatory approval or launching our product candidates, if approved; ● unstable market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole; ● price and volume fluctuations in the overall stock market; ● the failure of our product candidates, if approved, to achieve anticipated commercial success; in the time projected by securities analysts and others; ● announcements of **disruptions in supply and manufacturing of radioisotopes or raw materials required to manufacture radioisotopes, and any events that may disrupt the timely supply of radiopharmaceuticals to clinical sites; ● announcements of** the clinical success, NDA approval or introduction of new products by us or our direct competitors; ● announcements of developments concerning product development results or intellectual property rights of others; ● litigation or public concern about the safety and / or efficacy of our potential or approved products; ● actual fluctuations in our quarterly or annual operating results, and concerns by investors that such fluctuations may occur in the future and are indicative of internal problems; ● deviations in our operating results from the estimates of securities analysts or other analyst comments; ~~61~~ ● additions or departures of key personnel; ● healthcare reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third- party coverage and reimbursement policies; ● announcements or publicity concerning current or future strategic collaborations; ● discussion of our Company, our stock price or our potential future market value by the financial and scientific press and online investor communities; and ● market responses to the fluctuating conditions of COVID- 19 or **any future pandemics or** to the Russia- Ukraine **war or Israel- Hamas** war. We may become involved in securities class action litigation that could divert management' s attention and harm our business. The stock markets have from time- to- time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. Our stock price has experienced such fluctuations since our initial public offering. These broad market fluctuations may cause the market price of our stock to advance or decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management' s attention and resources, which could adversely affect our business. Substantial amounts of our outstanding shares may be sold into the market. If there are substantial sales of shares of our common stock, the price of our common stock could decline. The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our non- employee directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. We have ~~13, 193, 172~~ **17, 454, 925** outstanding shares of our common stock as of March ~~10~~ **8** , ~~2023~~ **2024** . A ~~majority~~ **substantial portion** of our outstanding shares of common stock are currently held by non- employee directors, executive officers and other affiliates and are subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (Securities Act). Our largest stockholders have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We have also registered shares of common stock that we have issued and may issue under our employee equity incentive plans. These shares are able to be sold freely in the public market upon issuance, subject to existing internal practices which prohibit sales under certain circumstances **and volume limitations for affiliates** . The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares. Our ability to use our net operating loss carry- forwards and certain other tax attributes may be limited. Under Section 382 of the Code, if a corporation undergoes an " ownership change " (generally

defined as a greater than 50 % change, by value, in its equity ownership over a three- year period), the corporation' s ability to use its pre- change net operating loss carry- forwards and other pre- change tax attributes (such as research tax credits) to offset its post- change income may be limited. We believe that additional fundraising efforts in the next three years, may trigger an " ownership change " limitation in the near future. As a result, if we earn net taxable income, our ability to use our pre- change net operating loss carry- forwards to offset U. S. federal taxable income will be subject to limitations, which could result in increased future tax liability to us had we not been subject to such limitations. ~~62If~~ **If** securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our Company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock. We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains as a return on their investments. There can be no assurance that we will ever provide liquidity to our investors through a sale of our Company. While acquisitions of pharmaceutical companies like ours are not uncommon, potential investors are cautioned that no assurances can be given that any form of merger, combination, or sale of our Company will take place or that any merger, combination, or sale, even if consummated, would provide liquidity or a profit for our investors. You should not invest in our Company with the expectation that we will be able to sell the business in order to provide liquidity or a profit for our investors. Delaware law and provisions in our amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the potential trading price of our common stock. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management or Board and adversely affect our stock price. Provisions of our amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, our amended and restated bylaws: ● provide that all vacancies on our Board may only be filled by our Board and not by stockholders; ● allow the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose; and ● provide that special meetings of our stockholders may be called only by our Board. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any " interested " stockholder for a period of three years following the date on which the stockholder became an " interested " stockholder. **Item 1C. Cybersecurity Like many companies, we face significant and persistent cybersecurity risks. The small size of our organization and limited resources could exacerbate these risks. However, we are committed to maintaining governance and oversight of these risks and to implementing standard operating procedures (" SOPs ") and training to help us assess, identify, monitor and respond to these risks. Some examples of procedures implemented include an internal inventory of software and database exposures, a risk analysis of database vendors, review of vendor back- up, security and privacy measures. In addition, we are in the process of drafting an internal cybersecurity policy which will be the basis for SOPs and training. Our internal server includes a firewall and is scanned for malware several times a day and the data is backed up in the Cloud for ease of restoration as needed. Employees are trained to avoid phishing emails and our internal controls system is designed to mitigate the risk of payments of fraudulent invoices. While we have not, as of the date of this Form 10- K, experienced cybersecurity threats, including as a result of a prior incident, that resulted in, or that we believe is reasonably likely to result in, a material adverse impact to our business strategy, results of operations or financial condition, there can be no guarantee that we will not experience a material incident in the future. Such incidents, whether successful or not, could impair our access to critical information including confidential operational and patient records and have the potential to be costly to effect remedies. See" Risk Factors" for more information on our cybersecurity risks. We aim to incorporate industry best practices for companies of our size and financial strength throughout our cybersecurity program. Our cybersecurity strategy focuses on implementing effective and efficient controls, technologies, and training programs to assess, identify, and manage material cybersecurity risks. Our Board of Directors has ultimate oversight of cybersecurity risk and has established a Cybersecurity committee headed by our Chief Financial Officer. As a small organization with limited resources, we do not have a dedicated cybersecurity organization or employee personnel with specific cybersecurity expertise. Our Chief Financial Officer was chosen to head our Cybersecurity committee due to more generalized management experience with financial and operating systems and oversight of third- party providers. Our Management team and our Board of Directors regularly review our cybersecurity program which generally occurs at least annually, or more frequently as determined to be necessary or advisable.**