Risk Factors Comparison 2025-03-21 to 2024-03-22 Form: 10-K

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Below is a summary of the principal factors that make an investment in our company speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below, after this summary, and should be carefully considered, together with other information in this Annual Report on Form 10- K and our other filings with the SEC before making an investment decision in our securities. Risks Related to Regulatory Approval and the Development and Commercialization of our Drug Candidates • We are developing our drugs to treat patients who are extremely or terminally ill, and patient deaths that occur in our clinical trials could negatively impact our business even if such outcomes are not shown to be related to our drugs. • We are conducting important clinical trials in the US and Europe, and **assessing** ~~studies for~~ additional countries in which to perform preclinical studies and clinical trials and the risks associated with conducting research and clinical trials abroad could materially adversely affect our business. • There are limited suppliers for active pharmaceutical ingredients (API) used in in our drug candidates and we utilize a single source for such API for certain of our drug candidates. Problems with the third parties that manufacture the API used in our drug candidates may delay our clinical trials or subject us to liability. • We cannot guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired. • Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for any of our product candidates. • As an organization, we have never **before** conducted pivotal clinical trials, and we may be unable to do so for any product candidate we may develop. • We may expend significant resources to pursue certain product candidates for specific indications and fail to capitalize on the potential of such product candidates for the potential treatment of other indications that may be more profitable or for which there is a greater likelihood of success. • We have commenced clinical trials and have never submitted an NDA, and any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval. • We may find it difficult to enroll subjects in our clinical trials, which could delay or prevent clinical trials of our product candidates. • A portion of our clinical development plan relies on physician- sponsored trials, which we do not control, and which may encounter delays for reasons outside of our control. • If any of our drug product candidates are found to be unsafe or lack sufficient efficacy, we will not be able to obtain regulatory approval for it and our business would be harmed. • Our product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales. • Even if our product candidates otherwise qualify for approval from the FDA, if the FDA does not find the manufacturing facilities of our future contract manufacturers acceptable for commercial production, we may not be able to commercialize any of our product candidates. • We received ODD for Annamycin, WP1066, and WP1122, but even if either product candidate is approved and receives ODE, ODE may not effectively prevent approval of a competing product. • **We may not be able to obtain or maintain rare pediatric disease designation or exclusivity for our product candidates, which could limit the potential profitability of our product candidates. •** The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential. • We have received Fast Track designation for two of our product candidates and may seek the same designation for one of more of our other product candidates. Even if we receive designation, such designation may not actually lead to a faster development or regulatory review or approval process. Fast Track designation may also be rescinded if the FDA believes the designation is no longer supported by data from our clinical development program. • Interim or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. • We may not be able to conduct, or contract others to conduct, animal testing in the future, which could harm our research and development activities. • We, or our third- party manufacturers, may be unable to successfully scale- up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any **. • Even if we obtain regulatory approvals for our product candidates, they will remain subject to ongoing regulatory oversight** . • Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize Annamycin and any future product candidates and may affect the prices we may set. Risks Related to Our Intellectual Property • The composition of matter patent for Annamycin has expired, and other patents have not yet been issued, and may not be issued. • The intellectual property rights we have licensed from MD Anderson are subject to the rights of the US government. • We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights. • We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. • If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished. • If we breach any of the agreements under which we license patent rights or if we fail to meet certain development deadlines, pay certain fees including extension fees or exercise certain rights to technology, we could lose or fail to obtain license rights that are important to our business. • We will not be able to protect our intellectual property rights throughout

the world. Risks Relating to Our Business and Financial Condition • We will require additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations. • Because successful development of our product candidates is uncertain, we are unable to estimate the actual amount of funding we will require to complete research and development and commercialize our products under development. • We have commenced clinical trials, have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance. • We have in the past completed related party transactions that were not conducted on an arm' s length basis. • We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability. • Our financial condition would be adversely impacted if our intangible assets become impaired. • We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third- party sales and marketing arrangements. • We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results. • We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. • We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth. • We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants. • We do not expect that our insurance policies will cover all of our business exposures thus leaving us exposed to significant uninsured liabilities. • We may incur penalties if we fail to comply with healthcare regulations. • We may not be able to recover from any catastrophic event affecting our suppliers. • Our business and operations would suffer in the event of third- party computer system failures, cyber- attacks on third- party systems or deficiency in our cyber security. • ~~The COVID- 19 outbreak delayed reenrollment in our clinical trials in the past and may return, may affect the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to our planned clinical trials and ultimately of reviews and approvals of our product candidates. •~~ Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. • We depend on our information technology and infrastructure so compromises could materially harm our ability to conduct business or delay our financial reporting. • We may be required to make significant payments under our license agreements with MD Anderson. • New tax laws or regulations that are enacted or existing tax laws and regulations that are interpreted, modified, or applied adversely to us or our customers may have a material adverse effect on our business and financial condition **. • We must comply with indirect tax laws in multiple jurisdictions, as well as complex customs duty regimes worldwide. Audits of our compliance with these rules may result in additional liabilities for taxes, duties, interest and penalties related to our international operations which would reduce our profitability. • Errors in our assumptions, estimates and judgments related to tax matters, including those resulting from regulatory reviews, could adversely affect our financial results. • We will require significant additional funding to complete the MIRACLE trial, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations** . Risks Relating to Our Common Stock • Our stock price has been and may continue to be volatile, which could result in substantial losses for investors ~~. • We are an early clinical stage biotechnology company and have incurred significant losses since our inception and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability, which could have an impact on finding additional financing~~ . • Shares issuable upon the exercise of outstanding options or warrants may substantially increase the number of shares available for sale in the public market and depress the price of our common stock. • As a biotechnology company, we are at increased risk of securities class action litigation. • If we are unable to maintain compliance with the listing requirements of The Nasdaq Capital Market, our common stock may be delisted from The Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares. • Failure to maintain our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies. • Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. • We cannot predict the effect that our reverse stock split will have on the market price for shares of our common stock. General Risks • Your ownership may be diluted if additional capital stock is issued to raise capital, to finance acquisitions or in connection with strategic transactions. • Negative research about our business published by analysts or journalists could cause our stock price to decline. A lack of regularly published research about our business could cause trading volume or our stock price to decline. • Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to us. • We have no intention of declaring dividends in the foreseeable future. • Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal data. • Certain provisions in our organizational documents could enable our board of directors to prevent or delay a change of control. • Shareholder activism could cause material disruption to our business. The following risks and uncertainties should be carefully considered. If any of the following occurs, our business, financial condition or operating results could be materially harmed. An investment in our securities is speculative in nature, involves a high degree of risk and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. We are developing our drug candidates to treat patients who are extremely or terminally ill, and severe adverse outcomes, including patient deaths, that occur in our clinical trials could negatively impact our business even if such outcomes are not shown to be related to our drugs. It is our intention to continue to develop our drug candidates focused on rare and deadly forms of cancer. Patients suffering from these diseases are extremely sick and have a high likelihood of experiencing adverse outcomes, including death, as a result of their disease or due to other significant risks

including relapse of their underlying malignancies. Many patients have already received high- dose chemotherapy and / or radiation therapy, which are associated with their own inherent risks, prior to treatment with our drug candidates. As a result, it is likely that we will observe severe adverse outcomes during our clinical trials for our drug candidates, including patient death. If a significant number of study subject deaths were to occur, regardless of whether such deaths are attributable to one of our drugs, our ability to obtain regulatory approval and / or achieve commercial acceptance for the related drug may be adversely impacted and our business could be materially harmed. We are conducting important clinical trials in the US and Europe, and **assessing** ~~we are performing studies for~~ additional countries in which to perform preclinical studies and clinical trials **,** and the risks associated with conducting research and clinical trials abroad could materially adversely affect our business. We have approved Clinical Trial Authorizations in Poland and Italy. Additionally, from time to time, we perform studies to determine if there are additional countries in which we should hold current and future clinical and preclinical studies. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including: • differing regulatory requirements in foreign countries; • unexpected changes in price and exchange controls and other regulatory requirements; • increased difficulties in managing the logistics and transportation of collecting and shipping patient material; • import and export requirements and restrictions; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses, and other obligations incident to doing business in another country; • difficulties staffing and managing foreign operations; • potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geo- political actions, including war and terrorism. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations **. There are limited suppliers for active pharmaceutical ingredients (API) used in our drug candidates and we utilize a single source for such API for certain of our drug candidates. Problems with the third parties that manufacture the API used in our drug candidates may delay our clinical trials or subject us to liability** . We do not currently own or operate manufacturing facilities for clinical or commercial production of the API used in any of our product candidates. We have no experience in API manufacturing, and we lack the resources and the capability to manufacture any of the APIs used in our product candidates, on either a clinical or commercial scale. As a result, we rely on third parties to supply the API used in each of our product candidates. For our lead product candidate, Annamycin, we currently utilize a single source to manufacture API, and if we were to lose this supplier, it could cause delays while we located a new supplier. We expect to continue to depend on third parties to supply the API for our current and future product candidates and to supply the API in commercial quantities. We are ultimately responsible for confirming that the APIs used in our product candidates are manufactured in accordance with applicable regulations. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including: • the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms; • reduced control as a result of using third- party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance. We do not have control over third party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures; • delays as a result of manufacturing problems or re- prioritization of projects at a third- party manufacturer; • our third- party manufacturers might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any; • termination or non- renewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; • the possible misappropriation of our proprietary information, including our trade secrets and know- how or infringement of third- party intellectual property rights by our contract manufacturers; and • disruptions to the operations of our third- party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier. Any of these events could lead to preclinical study and clinical trial delays or failure to obtain regulatory approval or affect our ability to successfully commercialize future products. Some of these events could be the basis for FDA or other regulatory authority action, including clinical holds, fines, injunctions, civil penalties, license revocations, recall, seizure, total or partial suspension of production, or criminal penalties. In addition, our product candidates involve technically complex manufacturing processes, and even slight deviations at any point in the production process may lead to production failures and may cause the production of our product candidates to be disrupted, potentially for extended periods of time. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. Furthermore, a contract manufacturer may possess technology related to the manufacture of our product candidate that such contract manufacturer owns independently. This would increase our reliance on such contract manufacturer or require us to obtain a license from such contract manufacturer in order to have another contract manufacturer manufacture our product candidates. Third- party manufacturers may not be able to comply with applicable cGMP regulations or similar regulatory requirements outside the US. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed, including clinical holds, fines, injunctions, civil penalties, delays, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. In addition, if we are required to change contract manufacturers for any reason, we will be required to verify that the new contract manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the

specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers, and it may prove very difficult and time consuming to identify potential alternative manufacturers who could manufacture our product candidates. Accordingly, we may incur added costs and delays in identifying and qualifying any such replacement. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. If our third- party drug suppliers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, we could be subject to certain product liability claims in the event such failure to comply resulted in defective products that caused injury or harm. Our business currently depends on the successful development and commercialization of our drug candidates. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of our drug candidates. We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of ~~a~~ **an** NDA from the FDA. We have not submitted any marketing applications for any of our product candidates. NDAs must include extensive preclinical and clinical data and supporting information to establish the product candidate' s safety and effectiveness for each desired indication. NDAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of ~~a~~ **an** NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is never guaranteed. If we submit a NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators in other jurisdictions have their own procedures for approval of product candidates. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply with prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn. If we are unable to obtain approval from the FDA, or other regulatory agencies, for any of our product candidates, or if, subsequent to approval, we are unable to successfully commercialize our product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations **. The development of our product candidates also may be delayed by other events beyond our control. For example, actions to limit federal agency budgets or personnel, may result in reductions to the FDA' s budget, employees, and operations, as well as changes to FDA regulatory programs, all of which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates, undergo regulatory inspections or obtain regulatory approval for our product candidates** . Any statements in this report indicating that any of our drug candidates have demonstrated preliminary evidence of efficacy are our own and are not based on the FDA' s or any other comparable governmental agency' s assessment and do not indicate that such drug candidate will achieve favorable efficacy results in any later stage trials or that the FDA or any comparable agency will ultimately determine that such drug candidate is effective for purposes of granting marketing approval. **Changes in funding for the FDA and other government agencies and the implementation of tariffs could prevent new products and services from being developed or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, payment of user fees and reauthorization of user fee programs, staffing and other resource limitations, ability to hire and retain key personnel, as well as statutory, regulatory and policy changes. In addition, funding of other government agencies that support research and development activities that pertain to FDA review, such as research to understand new technologies or establish new standards, is subject to the political process, which is inherently fluid and unpredictable. Such government agencies also have been subject to reductions in funding and downsizing of agency staffing levels, which could materially impact our business and operations. The current administration has implemented or proposed policies that may affect the FDA review process, including efforts to downsize the federal workforce, remove job elimination protections for federal workers, limit certain communications, and potentially impact user fee reauthorization. If political pressure or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could**

significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, a portion of our supply chain is located in countries that may be subject to new or increased tariffs, which could lead to increased costs to us. This exposure to international trade policies poses a risk to our operations and our financial condition. Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We do not know whether any future trials or studies of our other product candidates will begin on time or will be completed on schedule, if at all. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, including delays or shortages in available drug product, required clinical trial administrative actions, slower than anticipated subject enrollment, changing standards of care, availability or prevalence of use of a comparative drug or required prior therapy, clinical outcomes or financial constraints. For instance, delays or difficulties in subject enrollment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial. Clinical trials of a new product candidate require the enrollment of a sufficient number of subjects, including subjects who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria. Rates of subject enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, that include the age and condition of the subjects and the stage and severity of disease, the nature of the protocol, the proximity of subjects to clinical sites and the availability of effective treatments and / or availability of investigational treatment options for the relevant disease. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including: • inability to obtain sufficient funds required for a clinical trial; • inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • clinical sites dropping out of a clinical trial; • time required to add new clinical sites; • negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program; • serious and unexpected drug- related side effects experienced by subjects in our clinical trials or by individuals using drugs similar to our product candidates; • conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials; • delays in or inability to enroll research subjects in sufficient numbers or at the expected rate; • high drop- out rates and high fail rates of research subjects; • imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities; • delays or failures in obtaining required IRB approval; • inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials; failure to comply with GLP, GCP, cGMP or similar foreign regulatory requirements that affect the conduct of pre- clinical and clinical studies and the manufacturing of product candidates; • greater than anticipated clinical trial costs; • poor efficacy of our product candidates during clinical trials; • requests by regulatory authorities for additional data or clinical trials; • governmental or regulatory agency assessments of pre- clinical or clinical testing that differ from our interpretations or conclusions; • governmental or regulatory delays, or changes in approval policies or regulations; or • unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or vendor. We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations, cash flows and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. As an organization, we have never **before** conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop. We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, EMA or other regulatory agencies to market our product candidates. Carrying out pivotal clinical trials is a complicated process. As an organization, we have limited experience in successfully executing earlier- stage clinical trials, and **, prior to the MIRACLE trial currently underway,** we ~~have~~ **had** not previously conducted any later stage or pivotal clinical trials. In order to do so, we **are** ~~will need to expand~~ **expanding** our clinical development and regulatory capabilities, and we may be unable to **retain** ~~recruit and train~~ qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates. ~~We may expend significant~~ **Because we have limited financial and**

managerial resources ~~to pursue certain~~ **, we focus on research programs and** product candidates for specific indications ~~, and fail to capitalize on the potential of such product candidates for the potential treatment of other indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications~~ . Specifically, with regard to Annamycin, we are ~~initially~~ focusing our efforts on the treatment of AML and STS lung mets. As a result, we may forego or delay pursuit of opportunities with Annamycin or other product candidates for the treatment of other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Furthermore, until such time as we are able to build a broader product candidate pipeline, if ever, any adverse developments with respect to our current product candidates would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates. Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and our collaborators or we may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. The commencement and completion of future clinical trials could be substantially delayed or prevented by several factors, including, but not limited to: • **•** failure to reach agreement with the FDA or other regulatory agency requirements for clinical trial design or scope of the development program; a limited number of, and competition for, suitable subjects with particular types of cancer and viruses for enrollment in our clinical trials; • delays or failures in reaching acceptable clinical trial agreement terms with CROs or clinical trial sites; • delays or inability to attract clinical investigators for trials; • clinical sites dropping out of a clinical trial; • time required to add new clinical sites; • **•** • failure of subjects to complete the clinical trial or inability to follow subjects adequately after treatment; failures by, changes in our relationship with, or other issues at, CROs, vendors and investigators responsible for pre- clinical testing and clinical trials; imposition of a clinical hold; and • unforeseen safety issues. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit subjects to participate in testing our product candidates. If subjects are unwilling to participate in our trials because of ~~the COVID- 19 pandemic and restrictions on travel or healthcare institution policies,~~ negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. We may not be able to identify, recruit and enroll a sufficient number of subjects, or those with required or desired characteristics to achieve diversity in a clinical trial, or complete our clinical trials in a timely manner. Subject enrollment is affected by a variety factors including, among others: • severity of the disease under investigation; • design of the trial protocol and size of the patient population required for analysis of the trial' s primary endpoints; • size of the patient population; • eligibility criteria for the trial in question; • perceived risks and benefits of the product candidate being tested; • willingness or availability of subjects to participate in our clinical trials ~~(~~ **; • willingness of the investigators to accept the trial design,** including ~~due to~~ the ~~COVID- 19 pandemic)~~ **control arm, of the study** ; • proximity and availability of clinical trial sites for prospective subjects; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • availability of competing vaccines and / or therapies and related clinical trials; • efforts to facilitate timely enrollment in clinical trials; • our ability to obtain and maintain subject consents; • the risk that subjects enrolled in clinical trials will drop out of the trials before completion; • subject referral practices of physicians; and • ability to monitor subjects adequately during and after treatment. We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible subjects to participate in the clinical trials required by regulatory agencies. Even if we enroll a sufficient number of eligible subjects to initiate our clinical trials, we may be unable to maintain participation of these subjects throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those subjects. If we have difficulty enrolling and maintaining the enrollment of a sufficient number of subjects to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business. Our drug product candidate, WP1066, was in two physician- sponsored Phase 1 clinical trials, one for adult GBM and another for pediatric brain tumors. Our drug product candidate, Annamycin, is currently in a physician- sponsored Phase 1b / 2 clinical trial in Poland for the treatment of STS lung metastases. These physician- sponsored trials are an important part of our clinical development plan. Although we provide drug product and other minor supporting activities for these clinical trials, we are not otherwise directly involved in these physician- sponsored trials. As such, we are dependent on the institutions conducting the trials to proceed with such trials on a timely basis, and we have encountered unforeseen delays in our physician- sponsored trials. For example, in the first quarter of 2021, we were notified that the physician sponsoring our WP1066 trial in adult GBM was leaving MD Anderson and MD Anderson terminated that trial. While we are making arrangements to continue this research in additional physician- sponsored trials, research on

WP1066 in adult GBM has been delayed. We can provide no assurance that we will not encounter future delays with our physician- sponsored trials. In some instances, there can be significant variability in safety and / or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we or any of our potential future collaborators may conduct will demonstrate the consistent or sufficient efficacy and safety that would be required to obtain regulatory approval and market any products. If we are unable to bring any of our drug candidates to market, or to acquire other products that are on the market or can be developed, our ability to create long- term stockholder value will be limited. Significant adverse events caused by our product candidates or even competing products in development that utilize a common mechanism of action could cause us, an IRB or ethics committee, and / or regulatory authorities to interrupt, delay or halt clinical trials and could result in clinical trial challenges such as difficulties in subject recruitment, retention, and adherence, the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if any product candidates are approved, after the approved product has been marketed. In **clinical** trials, both with prior developers and with ours using Annamycin, subjects have experienced adverse events. There can be no assurance that other adverse events may not emerge related to our drug. Additional or unforeseen side effects from Annamycin or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The range and potential severity of possible side effects from oncology therapies such as our drug candidates are significant. If any of our drug candidates cause undesirable or unacceptable side effects in the future, this could interrupt, delay or halt clinical trials and result in the failure to obtain or suspension or termination of marketing approval from the FDA and other regulatory authorities or result in marketing approval from the FDA and other regulatory authorities only with restrictive label warnings or other limitations. If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products: • 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; • regulatory authorities may require us to take our approved product off the market; • 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 the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products. Even if our product candidates otherwise qualify for approval from the FDA, if the FDA does not find the manufacturing facilities of our future contract manufacturers acceptable for commercial production, we may not be able to commercialize our product candidates. We are currently utilizing contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of drug product candidates for our clinical trials. Additionally, even if our product candidates **would** otherwise qualify for approval from the FDA **based on results from preclinical and clinical trials** , we do not intend to manufacture the approved pharmaceutical products. We do not currently have agreements for the commercial manufacture of Annamycin or any of our other product candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient commercial supplies of Annamycin if it is approved. Additionally, the facilities used by any contract manufacturer to manufacture any of our product candidates must be the subject of a satisfactory inspection before the FDA approves the product candidate manufactured at that facility. We are completely dependent on these third- party manufacturers for compliance with the requirements of US and non- US regulators for the manufacture of our products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA' s cGMP requirements, and other requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls or other negative actions. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured our product candidates, including: • the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture our product candidates; • the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and • the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third- party manufacturer. Any of these factors could prevent or cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products. In 2017, we received notice that the FDA granted ODD for Annamycin for the treatment of AML and in 2020 we received notice that the FDA granted ODD for Annamycin for the treatment of soft tissue sarcomas. In February 2019, we received notice that the FDA granted ODD for WP1066 for the treatment of glioblastoma and later on for WP1122, as well. ODD from the FDA is available for drugs targeting diseases with less than 200, 000 cases per year. ODD **does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. However, ODD** may enable market exclusivity of 7 years from the date of approval of a NDA in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan drug exclusivity will not bar

approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Even if either Annamycin or WP1066 is approved and ODE is granted, we cannot know that the exclusivity will prevent approval of another product containing Annamycin and intended to treat AML or soft tissue sarcomas, or WP1066 and intended to treat glioblastoma, because any such subsequent product could be demonstrated to be clinically superior to Annamycin or WP1066. ~~Prior~~ **We received four rare pediatric disease designations for WP1066, but may not be able** to **obtain a rare pediatric disease priority review voucher if WP1066 is approved or obtain future rare pediatric disease designations for our product candidates, which could adversely affect our potential profitability. We have obtained rare pediatric disease designation from the FDA for WP1066 for the treatment of ependymoma, DIPG, medulloblastoma and atypical teratoid rhabdoid tumor. Under the FDA' s RPDPRV program, upon the approval of an NDA for the treatment of a rare pediatric disease, the sponsor of such application may be eligible for an RPDPRV that can be used to obtain priority review for a subsequent NDA or Biologics License Application (BLA). A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its application. If an RPDPRV is received, it may be sold or transferred an unlimited number of times and may have significant value. However, the FDA' s RPDPRV program began to sunset on December 20, 2024, upon Congress' failure to pass a continuing resolution package that included its reauthorization. Under the amended statutory sunset provisions, after December 20, 2024, the FDA may award an RPDPRV for an approved rare pediatric disease product application only if the sponsor has rare pediatric disease designation for the drug and if that designation was granted by December 20, 2024. After September 30, 2026, the FDA may not award any RPDPRVs. Congress may vote to reauthorize this program, but its future remains unknown at this time. Failure of Congress to reauthorize the program will limit our ability to obtain an RPDPRV if WP1066 is approved for the treatment any of the four pediatric cancer indications for which WP1066 received rare pediatric disease designation and may limit our ability to obtain future rare pediatric disease designations for our product candidates. Before** obtaining approval to commercialize a product candidate in any jurisdiction, we and our collaborators must demonstrate ~~with substantial evidence from well-controlled clinical trials, and~~ to the satisfaction of the FDA or comparable foreign regulatory agencies ~~,~~ that such product candidates are safe and effective for their intended uses **. The FDA requires " substantial evidence " to make a finding of effectiveness for any approval. Substantial evidence generally requires two adequate and well- controlled studies; however, in certain circumstances, substantial evidence may be based on a single, large, multicenter, adequate and well- controlled study together with confirmatory evidence** . Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the United States. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. We are conducting significant clinical trials of Annamycin in Europe based on discussions with local regulatory bodies, and our business strategy includes utilizing the results from these clinical trials in our FDA submissions. There is no assurance that the FDA will accept the results from these clinical trials, which could require us to ~~redo such~~ **conduct additional preclinical studies or clinical** trials **, either prior to or post- approval,** in order to receive approval of our product candidates in the United States. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming **and could impair our ability to generate revenue from future drug sales or other sources** . Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. **Even if we obtain regulatory approvals for our product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping and submission of safety and other post- market information. Any regulatory approvals that we receive for our product candidates may also be subject to a risk evaluation and mitigation strategy (REMS), limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.** We have received Fast Track designation for two of our product candidates and may seek the same designation for one of more of our other product candidates. Such designation may not actually lead to a faster development or regulatory review or approval process. Fast Track designation may also be rescinded if the FDA believes the designation is no longer supported by data from our clinical development program. If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. FDA granted Fast Track designation to Annamycin for STS lung metastases and WP1122 for GBM. If we seek Fast Track designation for other indications on either of these or another product candidate, we may not receive it from the FDA. Additionally, even if we receive Fast Track designation, Fast Track designation

does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA **review** procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA' s priority review procedures **or that we would ultimately obtain regulatory approval. We also are unable to predict the potential changes in regulatory interpretations or agency funding or staffing that may impact the FDA' s use or implementation of the Fast Track designation** . Interim or preliminary data from our clinical trials that we announce or publish from time to time may change as more subject data become available and are subject to audit and verification procedures that could result in material changes in the final data. We have in the past, and intend in the future, to publicly disclose preliminary data from our clinical trials, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data becomes available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us could result in volatility in the price of our common stock. In addition, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the approvability of the particular drug candidate and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug candidate or our business. If the interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our current or any our future drug candidate, our business, operating results, prospects or financial condition may be materially harmed. Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed. In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale- up activities. If we or any manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. In addition, the supply chain for the manufacturing of our product candidates is complicated and can involve several parties. If we were to experience any supply chain issues, ~~including as a result of the COVID- 19 pandemic,~~ our product supply could be seriously disrupted. **The U. S.** ~~At the federal level, in July 2021, the Biden administration released an~~ **and** ~~executive order, " Promoting Competition~~ **state governments have shown significant interest** in **establishing cost containment measures to limit** the ~~American Economy~~ **growth of government- paid health care costs** , ~~" with multiple provisions aimed at~~ **including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded** prescription drugs. **For example** ~~In response to Biden' s executive order~~ , **the Patient Protection and Affordable Care Act, as amended (the ACA), intended to reduce the cost of health care, and it has substantially changed the way health care is financed by both government and private insurers. While we cannot predict with certainty what impact** on ~~September 9~~ **federal and other reimbursement policies this legislation will have in general or on our business specifically** , ~~2021~~ **the ACA may result in downward pressure on pharmaceutical reimbursement** , ~~HHS released a Comprehensive Plan~~ **which could negatively affect market acceptance of, and the price we may charge** for ~~Addressing High Drug Prices~~ **, any products we develop** that ~~outlines principles for drug pricing reform~~ **receives regulatory approval. Legislative changes to** and ~~sets out a variety~~ **regulatory changes under the ACA remain possible, but the nature and extent** of **such** potential **additional changes are uncertain at this time** ~~legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles~~ . In addition, the Inflation Reduction Act (IRA), among other things, (1) directs **the Department of Health and Human Services (** HHS **)** to negotiate the price of certain high- cost, single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. ~~The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the~~

~~pharmaceutical industry.~~ Under the IRA, certain categories of drugs are excluded from price negotiations, including drugs that receive orphan drug designation as the only FDA- approved indication. While we have obtained orphan drug designation for Annamycin, if we seek additional indications, or fail to maintain our orphan drug status, we may become subject to the price negotiation process. This could reduce the ultimate price that we receive for Annamycin, which could negatively affect our business, results of operations, financial conditions, and prospects. ~~Further, in response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.~~ At the state level, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price ~~or patient~~ reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. ~~Legally mandated price controls on~~ **Further, some individual states have begun establishing Prescription Drug Affordability Boards to review high- cost drugs and, in some cases, set upper** payment **limits** ~~amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition, and prospects~~ . In ~~addition~~ **June 2024** , **the U. S. Supreme Court reversed its longstanding approach under the Chevron doctrine,** ~~regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and~~ which ~~suppliers~~ **provided for judicial deference to regulatory agencies, including the FDA. As a result of this decision, we cannot be sure whether there** will be ~~included in~~ **increased challenges to existing agency regulations or how lower courts will apply** ~~their~~ -- **the** ~~prescription drug and~~ **decision in the context of** other ~~healthcare programs~~ **regulatory schemes without more specific guidance from the U. S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA' s authority, lead to uncertainties in the industry, and disrupt the FDA' s normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA** . We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. We expect that the Affordable Care Act **, Inflation Reduction Act,** and other healthcare reform measures, including those that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from third- party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize Annamycin, if approved. Risks Related to our Intellectual Property We are pursuing additional patents with claims directed to Annamycin drug product formulations and the methods of use of Annamycin to treat relapsed or refractory AML and other conditions, and methods for its synthesis, as the composition of matter patent protection for Annamycin has expired. As a result, competitors may be able to offer and sell products so long as these competitors do not infringe any other patents that third parties or we hold, including formulation, synthesis and method of use patents. However, particularly with regard to products approved for more than one indication, method of use patents may not provide significant protection, because a competitor could obtain approval for only a non- protected use and thus come to market, where the product may legally be prescribed for the protected use, thus undermining the protection provided by the patent. Although off- label prescriptions may infringe our method of use patents, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. Off- label sales would limit our ability to generate revenue from the sale of Annamycin, if approved for commercial sale. We have obtained a royalty- bearing, worldwide, exclusive license to intellectual property rights, including patent rights related to our WP1066 Portfolio and WP1122 Portfolio drug product candidates from MD Anderson. Some of our licensed intellectual property rights from MD Anderson have been developed in the course of research funded by the US government. As a result, the US government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh- Dole Act of 1980. Government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the US government has the right to require us, or an assignee or exclusive licensee to such inventions, to grant licenses to any of these inventions to a third party if they determine that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; (iii) government action is necessary to meet requirements for public use under federal regulations; or (iv) the right to use or sell such inventions is exclusively licensed to an entity within the US and substantially manufactured outside the US without the US government' s prior approval. Additionally, we may be restricted from granting exclusive licenses for the right to use or sell our inventions created pursuant to such agreements unless the licensee agrees to additional restrictions (e. g., manufacturing substantially all of the invention in the US). The US government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the US government may acquire title in any country in which a patent application is not filed within specified time limits. Additionally, certain inventions are subject to transfer restrictions during the term of these agreements and for a period, thereafter, including sales of products or components, transfers to foreign subsidiaries for the purpose of the relevant agreements, and transfers to certain foreign third parties. If any of our intellectual property becomes subject to any of the rights or remedies available to the US government or third parties pursuant to the Bayh- Dole Act of 1980, this could impair the value of our intellectual property and could adversely affect our business. We may from time to time seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property. If we choose to enforce our patent rights against a party, then that individual or company has the right to ask the court to rule that such patents are invalid or

should not be enforced. Additionally, the validity of our patents and the patents we have licensed may be challenged if a petition for post grant proceedings such as inter- partes review and post grant review is filed within the statutorily applicable time with the US Patent and Trademark Office (USPTO). These lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party' s activities do not infringe our intellectual property rights. In addition, in recent years the US Supreme Court modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of a challenge of any patents we obtain or license. As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. We license all of our technology from MD Anderson, and we must meet various payment and other obligations under our license agreements with MD Anderson. Our license agreements generally require that we meet various milestones by certain dates, each of which generally requires the payment of additional fees, including extension fees. To date, we have been able meet such milestones, pay certain fees or have been able to enter into extensions with MD Anderson related to such milestones. However, our failure to meet any financial or other obligations under our license agreements in a timely manner could result in the loss of our rights to our core technologies. We are a party to a number of license agreements with MD Anderson under which we are granted rights to intellectual property that are critical to our business and we expect that we will need to enter into additional license agreements in the future with MD Anderson based on development work we are pursuing under a sponsored research agreement. With respect to inventions arising from our sponsored research agreement, MD Anderson has provided us with an option to negotiate a royalty- bearing, exclusive license to any invention or discovery that is conceived or reduced to practice. However, regardless of such option to negotiate, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue a program based on that technology. We are dependent on patents licensed with MD Anderson. Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These infringing products may compete with the product candidates we may develop, without any available recourse. The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Risks Relating to Our Business and Our Financial Condition We have used and we intend to use our current cash resources and the proceeds from any possible future offerings, to, among other uses, advance Annamycin, WP1122 and WP1066 for certain indications through clinical development, advancing the remainder of the existing portfolio through preclinical studies and into INDs or their equivalent, and sponsoring research at MD Anderson and HPI. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in order to

complete clinical development and commercialize Annamycin and WP1066. If the FDA or its EU equivalent requires that we perform additional nonclinical studies or clinical trials, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential approval of Annamycin would likely be delayed. Further, there can be no assurance that the costs we will need to incur to obtain regulatory approval of Annamycin will not increase. The amount and timing of our future funding requirements will depend on many factors, including but not limited to: • whether our plan for clinical trials will be completed on a timely basis and, if completed, whether we will be able to publicly announce results from our phase I / II clinical trials in accordance with our announced milestones; • whether the results of our clinical trials will be announced on a timely basis and, when announced, whether such results are in accordance with our expectations or our announced milestones; • whether we are successful in obtaining the benefits of FDA' s expedited development and review programs related to Annamycin or our other drug candidates; • the progress, costs, results of and timing of our clinical trials and also of our preclinical studies; • the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals; • the costs associated with securing and establishing commercialization and manufacturing capabilities; • market acceptance of our product candidates; • the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies; • our ability to maintain, expand and enforce the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights; • our need and ability to hire additional management and scientific and medical personnel; • the effect of competing drug candidates and new product approvals; • our need to implement additional internal systems and infrastructure, including financial and reporting systems; and • the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future. Some of these factors are outside of our control. Our existing capital resources are not sufficient to enable us to complete the development and commercialization of our product candidates, or to initiate any clinical trials or additional development work needed for any other drug candidates. Accordingly, we will need to raise additional funds in the future. We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. We are a clinical stage pharmaceutical company with a limited operating history. Our operations to date have been limited to acquiring our technology portfolio, preparing several drugs for authorization to conduct clinical trials and conducting Phase 1 ~~and 2~~ **through Phase 3** clinical trials. We have yet to receive regulatory approvals for any of our drug candidates. Additionally, we have a limited amount of drug supply and the amount of drug required may depend upon subject response and the need for additional, unplanned treatments, making it difficult to predict the total amount of drug required. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our operating results are expected to significantly fluctuate from quarter- to- quarter or year- to- year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include: • any delays in regulatory review and approval of our product candidates in clinical development, including our ability to receive approval from the FDA or the Polish authorities for our drugs in clinical trials; • delays in the commencement, enrollment and timing of clinical trials; • difficulties in identifying subjects suffering from our target indications; • the success of our clinical trials through all phases of clinical development; • potential side effects of our product candidates that could delay or prevent approval or cause an approved drug to be taken off the market; • our ability to obtain additional funding to develop drug candidates; • our ability to identify and develop additional drug candidates beyond Annamycin and our WP1066 and WP1122 Portfolios; • competition from existing products or new products that continue to emerge; • the ability of subjects or healthcare providers to obtain coverage or sufficient reimbursement for our products; • our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations (CROs); • our dependency on third- party manufacturers to manufacture our products and key ingredients; • our ability to establish or maintain collaborations, licensing or other arrangements, particularly with MD Anderson; • our ability to defend against any challenges to our intellectual property including, claims of patent infringement; • our ability to enforce our intellectual property rights against potential competitors; • our ability to secure additional intellectual property protection for our developing drug candidates and associated technologies; • our ability to attract and retain key personnel to manage our business effectively; and • potential product liability claims. Accordingly, the results of any historical quarterly or annual periods should not be relied upon as indications of future operating performance. Prior to our IPO, we acquired (i) the rights to the license agreement with MD Anderson covering our WP1122 Portfolio held by IntertechBio Corporation, a company affiliated with certain members of our management and board of directors, and (ii) the rights to all data related to the development of Annamycin held by AnnaMed, Inc., a company affiliated with certain members of our management and board of directors. In addition, prior to our IPO, Moleculin, LLC merged with and into our company. Moleculin, LLC was affiliated with certain members of our management and board of directors. Prior to our IPO, we, on Moleculin, LLC' s behalf, entered into an agreement with HPI whereby HPI agreed to terminate its option to sublicense certain rights to the WP1066 Portfolio and entered into a co- development agreement with us. Our co- founder, Dr. Waldemar Priebe, and a member of our management are shareholders of HPI. In addition, in February 2019, we entered into sublicense ~~agreements~~ **agreement** with ~~WPD Pharmaceuticals, Inc. (which was terminated in March 2023) and~~ Animal Lifesciences, LLC. ~~Dr. Priebe is affiliated with both WPD Pharmaceuticals, Inc. and Animal~~

~~Lifesciences, LLC. For the sublicense agreement (and the March 2021 amendment) with WPD Pharmaceuticals, Inc., since~~ Dr. Priebe was affiliated with ~~the entity, our board of directors received fairness opinions as to the adequacy of the consideration we received in the sublicense agreement (and the March 2021 amendment). Due to the increase in the required development efforts and the reduction in the buyback calculation in the amendment in December 2021, we did not receive a fairness opinion on that amendment. We also did not receive a fairness opinion on the transactions that occurred prior to our IPO or with~~ Animal Lifesciences, LLC **at the time these agreements were executed** . None of the foregoing transactions were conducted on an arm' s length basis. As such, it is possible that the terms were less favorable to us than in an arm' s length transaction. We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any drug candidates for approval by regulatory authorities in the United States or elsewhere. For the year ended December 31, ~~2023~~ **2024** , we incurred a net loss of $ ~~29~~ **21** . 8 million. We had an accumulated deficit of $ ~~131~~ **153** . ~~6~~ **4** million as of December 31, ~~2023~~ **2024** . To date, we have devoted most of our financial resources to research and development, including our drug discovery research, preclinical development activities and clinical trial preparation, as well as corporate overhead. We have not generated any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for Annamycin and our other drug candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our continuing product development efforts. We anticipate that any such losses could be significant for the next several years. If Annamycin, WP1066 or any of our other drug candidates fail in clinical trials or do not gain regulatory approval, or if our drug candidates do not achieve market acceptance, we may never become profitable. As a result of the foregoing, we expect to continue to experience net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. As a result of the accounting for our acquisition of Moleculin, LLC and the agreement we, on Moleculin, LLC' s behalf, entered into with Houston Pharmaceuticals, Inc., we have carried on our balance sheet within intangible assets in- process research and development (IPR & D) of $ 11. 1 million as of December 31, ~~2023~~ **2024** . Intangibles are evaluated quarterly and are tested for impairment at least annually or when events or changes in circumstances indicate the carrying value of each segment, and collectively our company taken as a whole, might exceed its fair value. Intangible assets related to IPR & D are considered indefinite- lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written- off and we will record a noncash impairment loss on our statement of operations. For those compounds that reach commercialization, if any, the IPR & D assets will be amortized over their estimated useful lives. If we determine that the value of our intangible assets is less than the amounts reflected on our balance sheet, we will be required to reflect an impairment of our intangible assets in the period in which such determination is made. An impairment of our intangible assets would result in our recognizing an expense in the amount of the impairment in the relevant period, which would also result in the reduction of our intangible assets and a corresponding reduction in our stockholders' equity in the relevant period. As the transactions discussed above were related party transactions and were not conducted on an arm' s length basis, it is possible that the terms were less favorable to us than what we would have received in an arm' s length transaction. We have no sales, marketing or distribution experience. To develop sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that Annamycin or any of our other product candidates will be approved by the FDA. For product candidates where we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including that we or our third- party sales collaborators may not be able to build and maintain an effective marketing or sales force. If we use third parties to market and sell our products, we may have limited or no control over their sales, marketing and distribution activities on which our future revenues may depend. Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we may seek to enter into collaborations with companies that have more experience. Additionally, if any of our product candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties. If we are unable to enter into arrangements on acceptable terms, if at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our product candidates. When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. One or more of our collaboration partners may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may contain provisions that are not favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for our product candidates, we would face increased costs, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them. As a result, we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition could be materially and adversely affected. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe and other jurisdictions, including major multinational pharmaceutical companies,

established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting subjects and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and / or FDA approval or discovering, developing and commercializing drugs for the diseases that we are targeting before we do or may develop drugs that are deemed to be more effective or gain greater market acceptance than ours. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. In addition, many universities and private and public research institutes may become active in our target disease areas. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than any of our product candidates that we are currently developing or that we may develop, which could render our products obsolete or noncompetitive. A number of attempts have been made or are under way to provide an improved treatment for AML. Drugs attempting to target a subset of AML patients who present with particular anomalies involving a gene referred to as FLT3 are currently in clinical trials. Other approaches to improve the effectiveness of induction therapy are in early- stage clinical trials and, although they do not appear to address the underlying problems with anthracyclines, we can provide no assurance that such improvements, if achieved, would not adversely impact the need for improved anthracyclines. A modified version of doxorubicin designed to reduce cardiotoxicity is in clinical trials for the treatment of sarcoma and, although this drug does not appear to address multidrug resistance and is not currently intended for the treatment of acute leukemia, we can provide no assurance that it will not become a competitive alternative to Annamycin. Although we are not aware of any other single agent therapies in clinical trials that would directly compete against Annamycin in the treatment of relapsed and refractory AML, we can provide no assurance that such therapies are not in development, will not receive regulatory approval and will reach market before our drug candidate Annamycin. In addition, any such competing therapy may be more effective and / or cost- effective than ours. If our competitors market products that are more effective, safer or less expensive or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, because of our limited resources, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. As we advance our product candidates through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we may need to increase our general and administrative capabilities. Our management, personnel, and systems currently in place may not be adequate to support this future growth. If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected. We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. We are highly dependent on the development, regulatory, commercialization and business development expertise of our management team, key employees, and consultants. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business. In addition, we have scientific and clinical advisors and consultants who assist us in formulating our research, development, and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non- compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. We do not carry insurance for all categories of risk that our business may encounter. There can be no assurance that we will secure adequate insurance coverage or that any such insurance coverage will be sufficient to protect our operations to significant potential liability in the future. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. Additionally, we use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time- consuming or costly. We do not carry specific hazardous waste insurance coverage and our property and casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. In addition to FDA restrictions on the marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device

industries in recent years, as well as consulting or other service agreements with physicians or other potential referral sources. These laws include anti- kickback statutes and false claims statutes that prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or, in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally-financed healthcare programs, and knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The majority of states also have statutes or regulations similar to the federal anti- kickback law and false claims laws, which apply to items and services, reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and any practices we adopt may not, in all cases, meet all of the criteria for safe harbor protection from anti- kickback liability. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer' s products from reimbursement under government programs, criminal fines and imprisonment. Any challenge to our business practices under these laws could have a material adverse effect on our business, financial condition and results of operations. Our suppliers may not have adequate measures in place to minimize and recover from catastrophic events that may substantially destroy their capability to meet customer needs, and any measures they may put in place may not be adequate to recover production processes quickly enough to support critical timelines or market demands. These catastrophic events may include weather events such as tornadoes, earthquakes, floods or fires. In addition, these catastrophic events may render some or all of the products at the affected facilities unusable. We rely on information technology (IT) systems, including third- party " cloud based " service providers, to keep financial records, maintain laboratory data, clinical data, and corporate records, to communicate with staff and external parties and to operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories and archives. If any of these third- party information technology providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyber- attacks or cyber- intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised, and we are unable to connect with third- party IT providers. 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. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and subjects enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third- party IT provider' s operation, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed or could fail ~~. The COVID- 19 outbreak delayed recruitment in clinical trials and may return. Additionally, it may delay the approvals of our product candidates due to its effect on the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned clinical trials. The spread of COVID- 19 may also slow potential enrollment of clinical trials and reduce the number of eligible subjects for our clinical trials. The COVID- 19 outbreak, and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID- 19 outbreak impacts our business and operations will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact. We have relationships with contract research organizations to conduct certain pre- clinical programs and testing and other services in Europe and those business operations are subject to potential business interruptions arising from protective measures that may be taken by the governmental or other agencies or governing bodies. In addition, certain of our collaborative relationships with research facilities and academic research institutions in the United States, Europe and in Australia may be materially and adversely impacted by protective measures taken by those institutions or federal and state agencies and governing bodies to restrict access to, or suspend operations at, such facilities. Such protective measures, including quarantines, travel restrictions and business shutdowns, may also have a material negative affect on our core operations~~ . We are subject to US data protection laws and regulations (i. e., laws and regulations that address privacy and data security) at both the federal and state levels. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. Numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of health-related and other personal information. In addition, we may obtain health information from third parties (e. g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under Health Insurance Portability and Accountability Act of 1996, or HIPAA. Although we are not directly subject to HIPAA- other than potentially with respect to providing certain employee benefits- we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. Finally, a data breach affecting sensitive personal information, including health information, could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. EU Member States, Switzerland and other countries have also adopted data protection laws and regulations, which impose significant compliance obligations. For example, the collection and use of personal health data in the EU is governed by the provisions of the EU Data Protection Directive, which was replaced by the General Data Protection Regulation (GDPR) in 2016 (Directive).

The Directive and the national implementing legislation of the EU Member States impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. Data protection authorities from the different E. U. Member States may interpret the Directive and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the EU. Guidance on implementation and compliance practices are often updated or otherwise revised. For example, the Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, that are not considered by the European Commission to provide an adequate level of data protection. These countries include the United States. The judgment by the Court of Justice of the EU in the Schrems case (Case C- 362 / 14 Maximillian Schrems v. Data Protection Commissioner) determined the US- EU Safe Harbor Framework, which was relied upon by many US entities as a basis for transfer of personal data from the EU to the US, to be invalid. US entities, therefore, had only the possibility to rely on the alternate procedures for such data transfer provided in the EU Data Protection Directive. On February 29, 2016, however, the European Commission announced an agreement with the US Department of Commerce, or DOC, to replace the invalidated Safe Harbor framework with a new EU- US " Privacy Shield ". On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the Court of Justice of the EU in its Schrems judgment by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and the Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. US companies have been able to certify to the DOC their compliance with the privacy principles of the Privacy Shield since August 1, 2016, and rely on the Privacy Shield certification to transfer of personal data from the EU to the US. On September 16, 2016, the Irish privacy advocacy group Digital Rights Ireland brought an action for annulment of the European Commission decision on the adequacy of the Privacy Shield before the Court of Justice of the E. U. (Case T- 670 / 16). Case T- 670 / 16 is still pending. If the Court of Justice of the EU invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to transfer personal data from the EU to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. US- based companies are permitted to rely either on their adherence to the EU- US Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the EU Data Protection Directive. In addition, the EU Data Protection Regulation, intended to replace the EU Data Protection Directive entered into force on May 24, 2016 and applied from May 25, 2018. The EU Data Protection Regulation introduced new data protection requirements in the E. U. and substantial fines for breaches of the data protection rules. The EU Data Protection Regulation increased our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with those data protection rules. Our failure to comply with these laws, or changes in the way in which these laws are implemented, could lead to government enforcement actions and significant penalties against us, and adversely impact our business. We rely on the efficient and uninterrupted operation of information technology systems, including mobile technologies, to manage our operations, to process, transmit and store electronic and financial information, and to comply with regulatory, legal and tax requirements. We also depend on our information technology infrastructure for communications among our personnel, contractors, consultants, and vendors. System failures or outages could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition. In addition, we depend on third parties to operate and support our information technology systems. These third parties vary from multi- disciplined to boutique providers, and they may or could have access to our computer networks, mobile networks, and our confidential information. Many of these third parties subcontract or outsource some of their responsibilities to other third parties. As a result, our information technology systems, including those functions that are performed by third parties who are involved with or have access to those systems, are very large and complex. Failure by any of these third- party providers to adequately deliver the contracted services, or maintain confidentiality, could have an adverse effect on our business, which in turn may materially adversely affect our operating results and financial condition. All information technology systems, despite implementation of security measures, may be vulnerable to disability, failures, or unauthorized access. If our information technology systems were to fail or be breached, such failure or breach could materially adversely affect our ability to perform critical business functions and sensitive and confidential data could be compromised. Under our agreements with MD Anderson associated with Annamycin, the WP1122 Portfolio and the WP1066 Portfolio, we are responsible for certain license, milestone and royalty payments over the course of the agreements. Annual license fees can cost as high as $ 0. 1 million depending upon the anniversary, milestone payments for the commencement of phase II and phase III clinical trials can cost as high as $ 0. 5 million. Other milestone payments for submission of an NDA to the FDA and receipt of first marketing approval for sale of a license product can be as high as $ 0. 6 million. Royalty payments can range in the single digits as a percent of net sales on drug products or flat fees as high as $ 0. 6 million, depending upon certain terms and conditions. If these milestone or other non- royalty obligations become due, we may not have sufficient funds available to meet our obligations. If we fail to meet our payment obligations, our license agreements could be terminated, which would materially and adversely affect our business operations and financial condition. New tax laws or regulations that are enacted or existing tax laws and regulations that are interpreted, modified or applied adversely to us or our customers may have a material adverse effect on our business and financial condition. New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us or our customers, which could adversely affect our business and financial condition. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act enacted many significant changes to the U. S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation

may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Any future tax legislation could increase our U. S. tax expense and could have a material adverse impact on our business and financial condition. **Our operations may be subject to audit by tax authorities in various countries. Many countries have indirect tax systems where the sale and purchase of goods and services are subject to tax based on the transaction value. These taxes are commonly referred to as value-added tax (" VAT ") or goods and services tax (" GST "). In addition, the distribution of our products subjects us to numerous complex customs regulations, which frequently change over time. Failure to comply with these systems and regulations can result in the assessment of additional taxes, duties, interest, and penalties. While we believe we are in compliance with local laws, we cannot assure that tax and customs authorities will agree with our reporting positions and upon audit such tax and customs authorities may assess additional taxes, duties, interest, and penalties against us. Adverse action by any government agencies related to indirect tax laws could materially and adversely affect our business, results of operations and financial condition. We may be subject to routine tax audits on various tax matters around the world in the ordinary course of business (including income tax, business tax, customs duties, sales and use tax, and value added tax (" VAT ") matters). We regularly assess the adequacy of our uncertain income tax positions and other reserves, which requires a significant amount of judgment. Although we may accrue for uncertain income tax positions and other regulatory audits, negotiations with taxing and customs authorities may lead to adjustments in excess of our accruals, resulting in liabilities for additional taxes, duties, penalties and interest. We have used and we intend to use our current cash resources and the proceeds from any possible future offerings, to, among other uses, advance our portfolio through preclinical studies and into INDs or their equivalent, and sponsoring research at MD Anderson and HPI. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We estimate that with our current cash on hand as of December 31, 2024, plus cash raised in the first quarter of 2025, will support our MIRACLE trial and our operations into the third quarter of 2025. As such, based on our current cash, in order to fund our operations beyond the near term, including MIRACLE, we will need to raise significant financing for which we have no commitments. If the FDA or its EU equivalent requires that we perform additional nonclinical studies or clinical trials, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential approval of Annamycin would likely be delayed. Further, there can be no assurance that the costs we will need to incur to obtain regulatory approval of Annamycin will not increase.** Risks Relating to Our Common Stock **Over the past two years** ~~Since our IPO in June 2016~~, our stock price has ranged from a high of $ ~~862~~ **30** . ~~20~~ **00** to a low of $ ~~5~~ **0** . ~~07~~ **42** (taking into account the reverse stock splits we have completed), and the market price of our common stock is likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control. In addition, the securities markets have from time- to- time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also significantly affect the market price of our common stock. ~~Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant operating losses since inception. We expect to continue to incur significant operating losses for the foreseeable future. To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. We may never succeed in these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. Our ability to continue our operations depends on our ability to complete equity or debt financings or generate profitable operations in the future and beyond the near term. Such financings may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that could result from the outcome of this uncertainty. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern.~~ As of December 31, ~~2023~~ **2024** , we had warrants and options outstanding to purchase an aggregate of ~~1~~ **8** , ~~621~~ **594** , ~~576~~ **561** shares of common stock at an average exercise price of $ ~~28~~ **4** . ~~65~~ **33** per share (taking into account the reverse stock splits we have completed). To the extent any of these options or warrants are exercised and any additional options or warrants are granted and exercised, there will be further dilution to stockholders and investors. Until the options and warrants expire, these holders will have an opportunity to profit from any increase in the market price of our common stock without assuming the risks of ownership. Holders of options and warrants may convert or exercise these securities at a time when we could obtain additional capital on terms more favorable than those provided by the options or warrants. The exercise of the options and warrants will dilute the voting interest of the owners of presently outstanding shares by adding a substantial number of additional shares of our common stock. Biotechnology companies have experienced greater than average stock price volatility in recent years, and our common stock price has been particularly volatile ranging from a high of $ ~~862~~ **30** . ~~20~~ **00** to a low of $ ~~5~~ **0** . ~~07~~ **42 over the past two years** (taking into account the reverse stock splits we have completed). These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of management would be diverted from the operation of our business. Our common stock is listed on The Nasdaq Capital Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly ~~-~~held shares, market value of listed shares, minimum bid price per share, and minimum stockholder' s equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from The Nasdaq Capital Market. We have in the past, and we may again in the future, fail to comply with the continued listing requirements of the Nasdaq Capital Market, which would subject our common stock to being delisted. Delisting from The Nasdaq Capital Market would adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors

to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities. As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes- Oxley Act of 2002, and the related rules and regulations of the SEC. Company responsibilities required by the Sarbanes- Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Because we are a smaller reporting company and a non- accelerated filer, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act. However, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in this report and future annual reports on Form 10- K, as required by Section 404 of the Sarbanes- Oxley Act. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have in the past, and may in the future, discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information. The global financial markets have recently experienced extreme volatility and 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. The financial markets, energy prices, and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets, energy prices, and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. We currently source the API for our lead product candidate, Annamycin, from a supplier in Europe and increased energy prices in the region may result in increased costs to us for such API. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to operate. On March 10, 2023, the Federal Deposit Insurance Corporation, or the FDIC, took control and was appointed receiver of Silicon Valley Bank, or SVB. We have no exposure to SVB. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. On March 22, 2024, we completed a one- for- fifteen reverse stock split of our shares of common stock. The reverse stock split was effected in accordance with the authorization adopted by our stockholders at a special meeting of stockholders held in October 2023. We cannot predict the effect that the reverse stock split will have on the market price for shares of our common stock, and the history of similar reverse stock splits for companies in like circumstances has varied. Some investors may have a negative view of a reverse stock split. Even if the reverse stock split has a positive effect on the market price for shares of our common stock, performance of our business and financial results, general economic conditions and the market perception of our business, and other adverse factors which may not be in our control could lead to a decrease in the price of our common stock following the reverse stock split. Even if the reverse stock split does result in an increased market price per share of our common stock, the market price per share following the reverse stock split may not increase in proportion to the reduction of the number of shares of our common stock outstanding before the implementation of the reverse stock split. Accordingly, even with an increased market price per share, the total market capitalization of shares of our common stock after the reverse stock split could be lower than the total market capitalization before the reverse stock split. Also, even if there is an initial increase in the market price per share of our common stock after the reverse stock split, the market price may not remain at that level. If the market price of shares of our common stock declines following the reverse stock split, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater than would occur in the absence of the reverse stock split due to decreased liquidity in the market for our common stock. Accordingly, the total market capitalization of our common stock following the reverse stock split could be lower than the total market capitalization before the reverse stock split **. There are provisions in certain of our outstanding warrants that could discourage an acquisition of us by a third party. Certain of our outstanding warrants provide that in the event of a " Fundamental Transaction " (as defined in the related warrant agreement, which generally includes any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of more than 50 % of our common stock), each warrant holder will have the right at any time**

prior to the consummation of the Fundamental Transaction to require us to repurchase the common warrant for a purchase price in cash equal to the Black- Scholes value (as calculated under the warrant agreement) of the then remaining unexercised portion of such warrant on the date of such Fundamental Transaction, which may materially adversely affect our financial condition and / or results of operations and may prevent or deter a third party from acquiring us . We intend to seek to raise additional funds, finance acquisitions or develop strategic relationships by issuing equity or convertible debt securities, which would reduce the percentage ownership of our existing stockholders. Our board of directors has the authority, without action or vote of the stockholders, to issue all or any part of our authorized but unissued shares of common or preferred stock. Our certificate of incorporation authorizes us to issue up to 100, 000, 000 shares of common stock and 5, 000, 000 shares of preferred stock. Future issuances of common or preferred stock would reduce your influence over matters on which stockholders vote and would be dilutive to earnings per share. In addition, any newly issued preferred stock could have rights, preferences and privileges senior to those of the common stock. Those rights, preferences and privileges could include, among other things, the establishment of dividends that must be paid prior to declaring or paying dividends or other distributions to holders of our common stock or providing for preferential liquidation rights. These rights, preferences and privileges could negatively affect the rights of holders of our common stock, and the right to convert such preferred stock into shares of our common stock at a rate or price that would have a dilutive effect on the outstanding shares of our common stock. The trading market for our common stock depends in part on the research and reports that analysts and journalists publish about us or our business. If analysts or journalists publish inaccurate or unfavorable research about our business, our stock price would likely decline. If we fail to meet the expectations of analysts for our operating results, or if the analysts who covers us downgrade our stock, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline. Our certificate of incorporation and bylaws contain provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, or DGCL, the personal liability of our directors and executive officers for monetary damages for breach of their fiduciary duties as a director or officer. Our certificate of incorporation and bylaws also provide that we will indemnify our directors and executive officers and may indemnify our employees and other agents to the fullest extent permitted by the DGCL. Any claims for indemnification made by our directors or officers could impact our cash resources and our ability to fund the business. The decision to pay cash dividends on our common stock rests with our board of directors and will depend on our earnings, unencumbered cash, capital requirements and financial condition. We do not anticipate declaring any dividends in the foreseeable future, as we intend to use any excess cash to fund our operations. Investors in our common stock should not expect to receive dividend income on their investment, and investors will be dependent on the appreciation of our common stock to earn a return on their investment. ~~Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal data.~~ Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third- party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business. Our organizational documents contain provisions that may have the effect of discouraging, delaying or preventing a change of control of, or unsolicited acquisition proposals, that a stockholder might consider favorable. These include provisions: • prohibiting the stockholders from acting by written consent; • requiring advance notice of director nominations and of business to be brought before a meeting of stockholders; • requiring a majority vote of the outstanding shares of common stock to amend the bylaws; and • limiting the persons who may call special stockholders' meetings. Furthermore, our board of directors has the authority to issue shares of preferred stock in one or more series and to fix the rights and preferences of these shares without stockholder approval. Any series of preferred stock is likely to be senior to our common stock with respect to dividends, liquidation rights and, possibly, voting rights. The ability of our board of directors to issue preferred stock also could have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock. In addition, Delaware law makes it difficult for stockholders that recently have acquired a large interest in a corporation to cause the merger or acquisition of the corporation against the directors' wishes. Under Section 203 of the Delaware General Corporation Law, a Delaware corporation may not engage in any merger or other business combination with an interested stockholder for a period of three years following the date that the stockholder became an interested stockholder except in limited circumstances, including by approval of the corporation' s board of directors. Publicly traded companies have increasingly become subject to campaigns by activist investors advocating corporate actions such as actions related to environment, social and governance (ESG) matters, among other issues. Responding to proxy contests and other actions by such activist investors or others in the future could be costly and time- consuming, disrupt our operations and divert the attention of our Board of Directors and senior management from the pursuit of our business strategies, which could adversely affect our results of operations and financial condition.