

Risk Factors Comparison 2025-03-31 to 2024-04-01 Form: 10-K

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An investment in our securities involves a high degree of risk. You should consider carefully all of the material risks described below, together with the other information contained in this Form 10-K. If any of the following events occur, our business, financial condition, results of operations and cash flows may be materially adversely affected. Risks Related to the Company's Business and Industry We will require substantial funding **in the near term to complete our clinical trials**, 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. We have used the proceeds from our previous ~~financing~~ **financings** to, among other uses, advance Berubicin through clinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in the near term in order to complete clinical development and commercialize **TPI 287 and** Berubicin. If the FDA 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 **TPI 287 and** Berubicin would likely be delayed. Further, there can be no assurance that the costs we will need to incur to obtain regulatory approval of **TPI 287 and** Berubicin will not increase. We will continue to require substantial additional capital to continue our clinical development and commercialization activities. 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 estimate that we **have sufficient capital to take us into the first quarter of 2026, a period during which we would likely expect to initiate a trial of TPI 287, as well as require additional financing of approximately \$ 15.0 to \$ 17.0 million to complete the potentially pivotal Phase 2 Berubicin trial including its further analysis for Berubicin (taking into account our cash on hand as of December 31, 2023 of approximately \$ 0. In 5 million) plus such additional -- addition, we have** working capital to fund our operations during **this period** the pendency of the trial (with such operations estimated at \$ 4.5 to \$ 5.0 million per annum). ~~If capital is~~ **We do not currently have a firm trial design for TPI 287 so estimates of development cost are not** available, **however, regardless of trial design, the cost of bringing TPI 287 to regulatory approval fund WP1244 / WP1874 preclinical work to prepare for marketing will require significant a Phase 1 trial, we would need to raise an additional financing \$ 5.0 million to support near-term development of that program.** The timing and costs of clinical trials are difficult to predict and as such the foregoing estimates may prove to be inaccurate. We have no commitments for such additional needed financing and will likely be required to raise such financing through the sale of additional equity or debt securities. 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; · whether we are successful in obtaining an accelerated approval pathway with the FDA related to Berubicin; · the progress, costs, results of and timing of our clinical trials for **TPI 287 and** Berubicin; · 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. 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. 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. The report of our independent registered public accounting firm expresses substantial doubt about our ability to continue as a going concern. Such “going concern” opinion could impair our ability to obtain financing. Our auditors have indicated in their report on our financial statements for the fiscal year ended December 31, ~~2023~~ **2024** that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses from operations. A “going concern” opinion could impair our ability to finance our operations through the sale of equity, incurring debt, or other financing alternatives. Our ability to continue as a going concern will depend upon the availability and terms of future funding. If we are unable to achieve this goal, our business would be jeopardized and we may not be able to continue. If we ceased operations, it is likely that all of our investors would lose their investment. Our success depends greatly on the success of **TPI 287 and** Berubicin's development for the treatment of glioblastoma, and our pipeline of product candidates beyond this lead indication is extremely early stage and limited. Other than **TPI 287 and** Berubicin, we do not have any other clinical- stage drug candidates in our portfolio. As such, we are dependent on the success of **TPI 287 and** Berubicin in the near term. We cannot provide you any assurance that we will be able to successfully advance **TPI 287 and** Berubicin through the development process or that we will be able to secure other

additional assets for development. ~~We have in the past completed related party transactions, some of which that were not conducted on an arm's length basis. We have entered into transactions with entities affiliated with our founder, Dr. Waldemar Priebe, including: We acquired the patent rights to Berubicin pursuant to a license agreement with Houston Pharmaceuticals, Inc. We entered into a sublicense agreement with WPD Pharmaceuticals, Inc., an entity with which Dr. Priebe is affiliated, which granted a WPD a license to Berubicin in a specified territory (primarily in eastern Europe and western Asia). We entered into a sublicense agreement with Animal Life Sciences, LLC ("ALI"), which granted an exclusive sublicense to Berubicin for the treatment of cancer in non-human animals. We entered into the above agreements related to Berubicin with HPI, WPD and ALI prior to our IPO, at a time during which we did not have an independent board of directors. As such, due to the related party relationship between our Company and these entities, the negotiation of these agreements was not conducted on an arm's length basis. As such, it is possible that the terms were less favorable to us than in a transaction negotiated in an arm's length transaction.~~ We have never been profitable, we have no products approved for commercial sale, and 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. Therefore, we may not be able to continue as a going concern. 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. Our ability to continue as a going concern is dependent upon our generating cash flow from sales that are sufficient to fund operations or finding adequate financing to support our operations. To date, we have had no revenues and have relied on equity-based financing from the sale of securities in public and private placements and the issuance of convertible notes. The continuation of the Company as a going concern is dependent upon our ability to obtain necessary equity or debt financing to continue operations and the attainment of profitable operations. As of December 31, ~~2023-2024~~ the Company has incurred an accumulated deficit of \$ ~~69-84, 566-424, 903-704~~ since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of December 31, ~~2023-2024~~, combined with capital raised subsequent to December 31, ~~2023-2024~~, is sufficient to fund its planned operations ~~into but not beyond~~ **within one year after the date that latter half of the second quarter of 2024 financial statements are issued**. To date, we have devoted most of our financial resources to corporate overhead, preparing for and conducting the clinical trial and marketing of our securities. 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 Berubicin and **TPI 287 WP1244 / WP1874**, 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 Berubicin 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. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our drug candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. We 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 are a clinical pharmaceutical company with limited operating history. Our operations to date have been limited to acquiring our technology portfolio, preparing for and conducting our Berubicin clinical trial, and ~~pre-~~ **preparing for and conducting our TPI 287 clinical trial work related to our other drug candidate, WP1244 / WP1874**. We have not yet obtained any regulatory approvals for any of our drug candidates. 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 for **TPI 287 and Berubicin**; · delays in the commencement, enrollment and timing of clinical trials; · difficulties in identifying patients suffering from our target indications; · the success of our clinical trials through all phases of clinical development; · potential side effects of our product candidate 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 Berubicin; · competition from existing products or new products that continue to emerge; · our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations (CROs); · our ability to establish or maintain collaborations, licensing, or other arrangements; · 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. These factors are our best estimates of possible factors but cannot be considered a complete recitation of possible factors that could affect the Company. Accordingly, the results of any historical quarterly or annual periods should not be relied upon as indications of future operating performance. We cannot be certain that **TPI 287 and Berubicin** will receive regulatory approval, and without regulatory approval we will not be able to market **TPI 287 and Berubicin**. Our business currently depends largely on the successful development and commercialization of **TPI 287 and Berubicin**. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of **TPI 287 and Berubicin** for the

treatment of glioblastoma. 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 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 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 an 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 Berubicin and our other product candidates, or if, subsequent to approval, we are unable to successfully commercialize Berubicin or our other product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations, likely resulting in the total loss of principal for our investors. Any statements in this filing indicating that **TPI 287 and** Berubicin has demonstrated preliminary evidence of efficacy are our own and are not based on the FDA's or any other comparable governmental agency's assessment of **TPI 287 and** Berubicin and do not indicate that **TPI 287 and** Berubicin will achieve favorable efficacy results in any later stage trials or that the FDA or any comparable agency will ultimately determine that **TPI 287 and** Berubicin is effective for purposes of granting marketing approval. 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 **TPI 287 and** Berubicin and our other product candidates. 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 study 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 patient 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 patient 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 patients, including patients who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria. The rates of patient 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 patients and the stage and severity of disease, the nature of the protocol, the proximity of patients 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, but not limited to:

- 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;
- 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;
- difficulty in enrolling research subjects in clinical trials including the inability to enroll any subjects at all;
- high dropout rates and high fail rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness of our product candidates during clinical trials; or
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or vendor. We have never completed a clinical trial or submitted an NDA before, and any product candidate we advance through

clinical trials may not have favorable results in later clinical trials or receive regulatory approval. 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. Many 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. 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. If **TPI 287 and Berubicin** is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be materially and possibly irreparably harmed. 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 adequate efficacy and safety that would be required to obtain regulatory approval and market any products. If we are unable to bring Berubicin 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.

~~The results of the interim analysis of our CNS-201 trial may not be indicative of the final results from this trial. We reached the criteria required by the study protocol for our CNS-201 trial to conduct a pre-planned, non-binding interim futility analysis, which an independent DSMB is responsible for conducting. The DSMB's charter mandated that they review the primary endpoint, Overall Survival, as well as secondary endpoints and safety data to determine whether the efficacy data for the risk-benefit profile warrants modification or discontinuation of the study. On December 18, 2023, we released the DSMB's recommendation which was to continue the study without modification. Management remains blinded to the data underlying the recommendation of the DSMB. The conclusions of the DSMB may not be indicative of the final results of our CNS-201 trial, which we expect to release in the first half of 2025, although it is impossible to accurately predict how long patients on the study may survive which could impact the timing of the release of final trial data.~~ 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 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 analysis 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 patient enrollment continues and more patient data become 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 shares 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. 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. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if **TPI 287 and Berubicin** (or our other product candidates) are approved, after the approved product has been marketed. The range and potential severity of possible side effects from therapies such as **TPI 287 and Berubicin** (or our other product candidates) are significant. If **TPI 287 and Berubicin** (or our other product candidates) causes 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. 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. 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, or such commercialization efforts may be delayed until we can contract with manufacturers with facilities acceptable to the FDA or other regulatory authorities. We do not have any manufacturing capabilities and we do not intend to manufacture the pharmaceutical products that we plan to sell. We utilize contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of drug product for our pre-clinical development and clinical trials of **TPI 287 and Berubicin** that we will need to conduct prior to seeking regulatory approval. However, we do not have agreements for supplies of **TPI 287 and Berubicin** or any of our other product candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to commercialize **TPI 287 or Berubicin** if ~~it is~~ **they are** approved. Additionally, the facilities used by any contract manufacturer to manufacture Berubicin or any of our other product candidates must be the subject of a satisfactory inspection before the FDA approves the product candidate manufactured at that facility. We will be completely dependent on these third-party manufacturers for compliance with the requirements of U. S. and non-U. S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and the FDA's current good manufacturing practice standards, or ~~eGMP-~~ **GMP**, 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. 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 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. We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into third-party sales and marketing arrangements, the problems with which could materially harm our business at any time. 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 Berubicin 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. 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. 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 with respect to our unlicensed territories. 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. 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, or the favorability of which is dependent on conditions that are out of our control or unknowable at the time of execution. 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. We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. The biotechnology and

pharmaceutical industries are 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 patients 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. 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. Our licensed U. S. patents for Berubicin expired in March 2020 and the patents for TPI 287 will expire before commercialization is reasonably possible, and the expiration of our patents may subject us to increased competition, and the Orphan Drug Designations we received for TPI 287 and Berubicin will not bar approval of other similar products under certain circumstances. The U. S. and foreign patents for TPI 287 will all expire in 2028 well before commercialization is reasonably possible. The U. S. patents for Berubicin that we previously licensed from HPI-Houston Pharmaceuticals, Inc. expired in March 2020, and such patent expiration expirations may subject us to increased competition. On TPI 287 held Orphan Drug Designation when we licensed it from Cortice and on June 10, 2020, the FDA granted Orphan Drug Designation (“ODD”) for Berubicin for the treatment of malignant gliomas. ODD from the FDA is available for drugs targeting diseases with less than 200, 000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of an 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. The ODD now constitutes our primary intellectual property protections although we are exploring if there are other patents that could be filed related to Berubicin to extend additional protections. The ODD similarly strengthens our TPI 287 patent protections and would become our primary protection upon expiration of those patents. However however , we are also exploring new patent opportunities related to TPI 287. Nevertheless , we can provide no assurance that we will be able to file or receive additional patent protection. The failure to obtain additional patent protection will reduce the barrier to entry for competition for TPI 287 or Berubicin, which may adversely affect our operations. We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights. 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 U. S. 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 U. S. 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. We may be subject to claims that our employees and contractors have wrongfully used or disclosed alleged trade secrets of their former employers. 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. 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. 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, 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 will need to expand our operations and increase the size of our Company, and we may experience difficulties in managing growth. As of ~~April 1, 2024~~ **March 31, 2025**, we have ~~3~~ **four** full-time employees. We also have ~~2~~ **1** ~~officers~~ **officer** serving as part-time ~~employees~~ **employee**. 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 manage our business effectively if we are unable to attract and retain key personnel and consultants. 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. 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 noncompete 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. Our chief ~~medical officer and chief science officer~~ **are** ~~is~~ currently working for us on a part-time basis. Our chief executive officer, ~~chief medical officer~~ and chief science officer, also provide services for other companies in our industry and such other positions may create conflicts of interest for such officers in the future. Certain of our key employees are currently part-time and / or provide services for other biotechnology development efforts, including companies, with respect to our chief executive officer and chief ~~medical~~ **science** officer, which are developing anti-cancer drug candidates. Specifically, John M. Climaco, our chief executive officer, is also serving as a director for Moleculin Biotech, Inc., a company also actively developing anticancer drugs. ~~Sandra Silberman, our chief medical officer, is also the chief medical officer for New Products at Moleculin.~~ Donald Picker, our chief science officer, is the chief scientific officer at Moleculin. In addition to our officers' part-time status, since Mr. Climaco, ~~Dr. Silberman~~ and Dr. Picker are associated with other companies that are developing anti-cancer drug candidates, they may encounter conflicts of interest in the future. Although we do not believe that the drug candidates we are currently pursuing compete with the types of drug candidates being pursued by the other companies Mr. Climaco, ~~Dr. Silberman~~ and Dr. Picker are associated with, there is no assurance that such conflicts will not arise in the future. We do not expect that our insurance policies will cover all of our business exposures thus leaving us exposed to significant uninsured liabilities. 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. Although dependent on certain key personnel, we do not have any key man life insurance policies on any such people. We are dependent on John M. Climaco, Christopher Downs, Sandra Silberman, and Donald Picker in order to conduct our operations and execute our business plan, however, we have not purchased any insurance policies with respect to those individuals in the event of their death or disability. Therefore, if any of John M. Climaco, Christopher Downs, Sandra Silberman, or Donald Picker die or become disabled, we will not receive any compensation to assist with such person's absence. The loss of such person could negatively affect us and our operations. There are limited suppliers for active pharmaceutical ingredients ("API") used in our drug candidates. Problems with the third parties that manufacture the API used in our drug candidates, or in the supply chain between the manufacturer and CNS, 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 drug 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 drug 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 drug candidates and commercial couriers to deliver the manufactured API to us. 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. Our third-party suppliers and couriers may not carry out their contractual obligations or meet our deadlines. In addition, the API they

supply to us may not meet our specifications and quality policies and procedures or they may not be able to supply the API in commercial quantities. If we need to find alternative suppliers for the API used in any of our product candidates, we may not be able to contract for such supplies on acceptable terms, if at all. Any such failure to supply or delay caused by such contract manufacturers or couriers would have an adverse effect on our ability to continue clinical development of our product candidates or commercialization of our product candidates. 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 product that caused injury or harm. We may not be able to recover from any catastrophic event affecting our suppliers. 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 have 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 and geologic events such as tornadoes, earthquakes, floods, tidal waves, volcanic eruptions, and fires as well as infectious disease epidemics, acts of war, acts of terrorism and nationalization of private industry. In addition, these catastrophic events may render some or all of the products at the affect facilities unusable. We may be materially adversely affected in the event of cyber- based attacks, network security breaches, service interruptions, or data corruption. We rely on information technology to process and transmit sensitive electronic information and to manage or support variety of business processes and activities. We use technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third parties, may be susceptible to damage, disruptions or shut down student computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, technology for communication failures, user errors or catastrophic events. Although we have developed systems and processes that are designed to protect proprietary or confidential information and prevent data loss and other security breaches, such measures cannot provide absolute security. If our systems are breached or suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may significantly suffer and we may be subject to litigation, government enforcement actions or potential liability. Security breaches could also cause us to incur significant remediation costs, result in product development delays, disrupt key business operations, including development of our product candidates, and divert attention of management and key information technology resources. Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail. We regularly maintain cash balances at third- party financial institutions in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance limit. Events involving limitations to liquidity, defaults, non- performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, the FDIC, took control and was appointed receiver of Silicon Valley Bank (to which the Company had no exposure). 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. Risks Related to Our Common Stock Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act has caused and may cause in the future our financial reports to be inaccurate. We are required pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, or Section 404, to maintain internal control over financial reporting and to assess and report on the effectiveness of those controls. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our management concluded that our internal controls over financial reporting were, and continue to be, ineffective as of December 31, ~~2023~~ **2024**, identified a material weakness in our internal controls due to the lack of sufficient personnel to allow for segregation of duties (resulting from the limited number of personnel available), limited access to timely and complete information regarding the status of costs incurred in the activation of investigational sites and costs from treating patients in our study which is a result of the use of a third- party Contract Research Organization (“ CRO ”) to manage the study, and the lack of formal documentation of our control environment. ~~As a result of the material weakness with the third- party CRO, the Company corrected previously issued financial statements for the periods ended December 31, 2021, March 31, 2022, June 30, 2022, and September 30, 2022 to properly reflect research and development expenses and the related liability in these periods that were previously not recorded.~~ While management is working to remediate the material weaknesses, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business. Failure to continue improving our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies. 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. Management performed an annual assessment as of December 31, ~~2023~~ **2024** of the effectiveness of our internal control over financial reporting for its annual report. Our management concluded that our internal control over financial reporting was, and continues to be, ineffective as of December 31, ~~2023~~ **2024**, due to material weaknesses in our internal controls due to the lack of segregation of duties (resulting from the limited number of personnel available), limited access to timely and complete information regarding the status of costs incurred in the activation of investigational sites

and costs from treating patients in our study which is a result of the use of a third- party Contract Research Organization (“CRO”) to manage the study, and the lack of formal documentation of our control environment. For as long as we remain an “emerging growth company” as defined in the JOBS Act, we have and intend to consider to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act. We may continue to take advantage of these reporting exemptions until we are no longer an “emerging growth company.” To mitigate the lack of segregation of duties material weaknesses, we engaged an outside firm to assist management with such accounting and will continue to use outside firms as a resource to deal with other non- recurring or unusual transactions. However, notwithstanding our mitigation efforts, there is no assurance we will not encounter accounting errors in the future. 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. Our current stockholders’ ownership may be diluted if additional capital stock is issued to raise capital, to finance acquisitions or in connection with strategic transactions. 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 articles of incorporation authorize us to issue up to ~~75~~**300**, 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. ~~In May 2020, the SEC issued an order suspending the trading of our common stock and Nasdaq issued a trading halt in our common stock. On May 1, 2020, the SEC, pursuant to Section 12 (k) of the Exchange Act, ordered the temporary suspension of trading in our securities because of questions regarding the accuracy and adequacy of information in the marketplace about us and our securities. Pursuant to the suspension order, the suspension commenced at 9: 30 a. m. EDT on May 4, 2020 and terminated at 11: 59 p. m. EDT on May 15, 2020. On May 15, 2020, Nasdaq issued a trading halt in our common stock pending the receipt of requested information, which halt was released on May 28, 2020. We believe ~~have~~ in the ~~past been~~ accuracy and adequacy of our public disclosures, but can provide no assurances that we will not encounter future similar actions, which may adversely affect the holders of our common stock. If we are unable to maintain compliance with the listing requirements of The Nasdaq Capital Market, ~~and any future failure to maintain compliance could subject~~ our common stock ~~may to~~ 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. 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. ~~During 2024~~ We have in the past, and we may again ~~were not~~ in ~~compliance~~ the future, fail to comply with the ~~requirement to maintain a closing bid price of \$ 1. 00 per share (the “ Minimum Bid Price Requirement ”) pursuant to Nasdaq Listing Rule 5550 (a) (2), and we were not in compliance with the minimum \$ 2, 500, 000 stockholders’ equity requirement for~~ continued listing ~~set forth~~ requirements of the Nasdaq Capital Market, which would subject our common stock to being delisted. In particular, on August 17, 2023, we received a letter (the “ Letter ”) from the staff of the Listing Qualifications Department (the “ Staff ”) of Nasdaq which notified us that we were not in compliance with Nasdaq’s Listing Rule 5550 (b) (~~1~~ the “ Equity Requirement ”). As of the date of this filing, we are in compliance with both requirements. However, with respect to the Equity Requirement, pursuant to Nasdaq Listing Rule 5815 (d) (4) (B), we are subject to a Mandatory Panel Monitor until September 10, 2025. If, within that monitoring period, the “ Staff finds us again out of compliance with the Equity Requirement, notwithstanding Listing Rule “ 5810 (c) (~~1~~ , which requires that we maintain a minimum of \$ ~~2~~) ~~5~~ million in stockholders’ equity, and that we will also did not ~~be permitted~~ , at such time, meet the alternatives of market value of listed securities or net income from continuing operations set forth in the Listing Rule. The Letter did not have any immediate effect on the listing of our common stock on Nasdaq and we had 45 calendar days to submit ~~provide~~ the Staff with a plan ~~of to regain~~ compliance . We ~~with respect to that deficiency and Staff will not be permitted to grant additional timely -- time for us submitted our plan to regain compliance with the respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Listing Rule , our plan was accepted and~~ 5810 (c) (3). With respect to the Staff granted an extension until ~~Minimum Bid Price Requirement, since we completed a reverse split on February 13 21 , 2024 2025 , if we fall out of (the “ Extension Period ”) to evidence compliance . On with the Minimum Bid Price Requirement prior to February 14 21 , 2024 2026 , we will~~ the Staff notified the Company that it had not ~~be eligible for any complied-- compliance with the period specified in Listing Rule 5810 (c) (3) (A) and as such did not meet the terms of the extension. The In either case described in the preceding two sentences, the Staff will issue a Delist Determination letter Letter~~ stated that unless the Company timely ~~and we will have an opportunity to requests- request~~ a hearing before a Hearings Panel (the “ Panel ”), the Company would be subject to delisting. ~~Our common stock may be at~~ Accordingly, the Company timely requested a hearing before the Panel, with such hearing scheduled for April 18, 2024. The hearing request automatically stayed any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. In that ~~time be delisted from Nasdaq~~ regard, the Panel has the discretion to~~

grant the Company an extension not to exceed August 12, 2024. Notwithstanding, there **There** can be no assurance that **we** the Panel will grant **continue to meet** the Company a further extension or that the Company will ultimately regain compliance with all applicable requirements for continued listing on **requirements of** The Nasdaq Capital Market **and could be subject to delisting at a future time**. 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. We may be required to repurchase certain of our warrants upon a fundamental transaction, which may prevent or deter a third party from acquiring us. Certain of our warrants to purchase common stock 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 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 common 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.

General Risk Factors As a biotechnology company, we may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business. If securities or industry analysts do not publish research or reports about us, or if they adversely change their recommendations regarding our common stock, then our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us, our industry and our market. If no analyst elects to cover us and publish research or reports about us, the market for our common stock could be severely limited and our stock price could be adversely affected. As a small- cap company, we are more likely than our larger competitors to lack coverage from securities analysts. In addition, even if we receive analyst coverage, if one or more analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. If one or more analysts who elect to cover us issue negative reports or adversely change their recommendations regarding our common stock, our stock price could decline. As an “emerging growth company” under the Jumpstart Our Business Startups Act, or JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. As an “emerging growth company” under the JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. We are an emerging growth company until the earliest of: · the last day of the fiscal year during which we have total annual gross revenues of \$ 1. 235 billion or more; · the last day of the fiscal year following the fifth anniversary of our IPO, which occurred in November 2019; · the date on which we have, during the previous 3- year period, issued more than \$ 1 billion in non- convertible debt; or · the date on which we are deemed a “large accelerated issuer” as defined under the federal securities laws. For so long as we remain an emerging growth company, we will not be required to: · have an auditor report on our internal control over financial reporting pursuant to the Sarbanes- Oxley Act of 2002; · comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis); · submit certain executive compensation matters to shareholders advisory votes pursuant to the “say on frequency” and “say on pay” provisions (requiring a non- binding shareholder vote to approve compensation of certain executive officers) and the “say on golden parachute” provisions (requiring a non- binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010; · include detailed compensation discussion and analysis in our filings under the Securities Exchange Act of 1934, as amended, and instead may provide a reduced level of disclosure concerning executive compensation; · may present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations, or MD & A; and · are eligible to claim longer phase- in periods for the adoption of new or revised financial accounting standards under § 107 of the JOBS Act. We intend to take advantage of all of these reduced reporting requirements and exemptions, other than the longer phase- in periods for the adoption of new or revised financial accounting standards under § 107 of the JOBS Act. Certain of these reduced reporting requirements and exemptions were already available to us due to the fact that we also qualify as a “smaller reporting company” under SEC rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding management’s assessment of internal control over financial reporting; are not required to provide a compensation discussion and analysis; are not required to provide a pay- for- performance graph or CEO pay ratio disclosure; and may present only two years of audited financial statements and related MD & A disclosure. We cannot predict if investors will find our securities less attractive due to our reliance on these exemptions. If investors were to find our common stock less attractive as a result of our election, we may have difficulty raising financing in the future. Item 1B. Unresolved Staff Comments.