Risk Factors Comparison 2025-03-27 to 2024-04-01 Form: 10-K

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An investment in shares of our common stock is highly speculative and involves a high degree of risk. We face a variety of risks that may affect our operations and financial results and many of those risks are driven by factors that we cannot control or predict. Before investing in our common stock you should carefully consider the following risks, together with the financial and other information contained in this report. If any of the following risks actually occurs, our business, prospects, financial condition and results of operations could be materially adversely affected. In that case, the trading price of our common stock would likely decline and you may lose all or a part of your investment. Only those investors who can bear the risk of loss of their entire investment should invest in our common stock. Risk Factor ~~Summary~~ **SummaryWe** ~~We~~ are providing the following summary of the risk factors contained in this Annual Report on Form 10- K to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Annual Report on Form 10- K in their entirety for additional information regarding the material **. ● Our exploration and pursuit of strategic alternatives may not be successful. ● In the event that we do not successfully identify a viable strategic option or, consummate such a transaction, or if we are unable to raise sufficient capital to fund our operations and commercialize Bryostatin- 1, our board of directors may determine that a liquidation and dissolution of our business approved by stockholders is the best method to seek to maximize stockholder value. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities** . ● If we continue to execute our current development strategy, we will need additional financing to fund our operations in the future. If we are unable to obtain additional financing on acceptable terms, we will need to curtail or cease our development plans and operations. ● Our ongoing viability as a company depends on our ability to successfully develop and commercialize our licensed technology. If the CRE License were terminated, we may be required to cease operations. ● We rely on independent third- party contract research organizations to perform clinical and non-clinical studies of our drug candidate and to perform other research and development services. ● We have relied on the representations and materials provided by CRE, including scientific, peer- reviewed and non- peer reviewed publications, abstracts, slides, internal documents, verbal communications, patents and related patent filings, with respect to the results of its research related to our proposed products. ● We have a limited operating history upon which investors can evaluate our future prospects. ● The commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, but not limited to, reasons related to the business, the economy and industry and government regulations. ● Data from our Bryostatin- 1 Phase 2 clinical trial, from our confirmatory Phase 2 clinical trial and our expanded Phase 2 clinical trial may be subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share the Company' s views of the data. ● We have not generated any revenues since our inception and we do not expect to generate revenue for the foreseeable future. If we do not generate revenues and achieve and sustain profitability, we will likely need to curtail or cease our development plans and operations. ● We are dependent on Dr. Alan Tuchman, M. D., our Chief Executive Officer, for the successful execution of our business plan. The loss of Dr. Tuchman or other key members of our management team could have a material adverse effect on our business prospects. ● We may not be able to protect our trade secrets and other unpatented proprietary technologies, which could give our competitors an advantage over us. ● We are partly dependent upon the NCI to supply bryostatin for our clinical trials. ● We expect to rely on third parties to manufacture our proposed products and, as a result, we may not be able to control our product development or commercialization. **38** ● We may rely on third parties for marketing and sales and our revenue prospects may depend on their efforts. ● If our products are not accepted by patients, the medical community or health insurance companies, our business prospects will suffer. ● The branded prescription segment of the pharmaceutical industry in which we operate is competitive, and we are particularly subject to the risks of such competition. ● A successful liability claim, such as a clinical trial liability claim, against us could have a material adverse effect on our financial condition even with such insurance coverage. ● Disruptions in federal government operations or extended government shutdowns may negatively impact our business. ● Our business and operations would suffer in the event of computer system failures ~~. ● The impact of the COVID- 19 pandemic, the shift to a COVID- 19 endemic approach and related risks could materially affect our results of operations, financial position and / or liquidity~~ . ● We are currently operating in a period of economic uncertainty and capital markets disruption. ● Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act could materially and adversely affect us. ● In connection with our separation from Neurotrope, we have agreed to indemnify Neurotrope for certain liabilities which could negatively impact our financial positions. ● ~~Increasing scrutiny and evolving expectations from customers, regulators, investors, and other stakeholders with respect to our environmental, social and governance (ESG) practices may impose additional costs on us or expose us to new or additional risks. ●~~ We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure ~~. ● We are subject to risks related to corporate and social responsibility and reputation. ● Our Common Stock has only recently become traded on the Nasdaq Capital Market (" Nasdaq "), and the market price of our common stock has been volatile. ● The requirement that we redeem the Series B Preferred Stock (as defined below) in cash could adversely affect our business plan, liquidity, financial condition, and results of operations. ● The terms of the Series B Preferred Stock could limit our growth and our ability to finance our operations, fund our capital needs, respond to changing conditions and engage in other business activities that may be in our best interests~~ . ● If our shares of Common Stock

become subject to the penny stock rules, it would become more difficult to trade our shares. ● A significant number of our shares of Common Stock are or will be eligible for future sale, which may cause the market price for our Common Stock to decline. ~~41~~ ● We do not expect to pay any cash dividends for the foreseeable future. ● Provisions in our certificate of incorporation, our bylaws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our Common Stock. ● We have identified material weaknesses in our internal control over financial reporting, which could negatively impact on our ability to report our results of operations and financial condition accurately and in a timely manner. ● You may experience dilution of your ownership interests because of the future issuance of additional shares of our Common Stock. Further, we may obtain additional capital through the issuance of preferred stock, which may limit your rights as a holder of our Common Stock. ● We are an " emerging growth company, " and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors. **39Risks Related to Our Evaluation of Strategic AlternativesOur exploration and pursuit of strategic alternatives may not be successful. In December 2024, our board of directors formed an independent special committee (the " Special Committee ") to explore strategic opportunities to create and enhance value for investors, including promising drug development platforms and / or compelling new technologies and services with the goal of maximizing stakeholder value. Despite our plan to devote significant efforts to identify and evaluate potential strategic options, the process may not result in any definitive offer to consummate such a transaction, or, if we receive such a definitive offer, the terms may not be as favorable as anticipated or may not result in the execution or approval of a definitive agreement. Even if we enter into a definitive agreement, we may not be successful in completing a transaction or, if we complete such a transaction, it may not enhance stockholder value or deliver expected benefits. Since we may not ultimately pursue or consummate a strategic transaction, we have begun to evaluate other options for maximizing the value of Bryostatin- 1, which may include seeking to raise capital to support the commercialization of Bryostatin- 1. In the event that we do not successfully identify a viable strategic option or, consummate such a transaction, or if we are unable to raise sufficient capital to fund our operations and commercialize Bryostatin- 1, our board of directors may determine that a liquidation and dissolution of our business approved by stockholders is the best method to seek to maximize stockholder value. In the event that we do not successfully identify a viable strategic option or, consummate such a transaction, or if we are unable to raise sufficient capital to fund our operations and commercialize Bryostatin- 1, our board of directors may determine that a liquidation and dissolution of our business approved by stockholders is the best method to seek to maximize stockholder value. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities. There can be no assurance that the process to identify a strategic alternative for our business will result in a successfully consummated transaction. If we are unable to identify a viable strategic option or if such a transaction is not completed in a timely manner, or if we are unable to raise sufficient capital to fund our operations and commercialize Bryostatin- 1, our board of directors may determine that a liquidation and dissolution of our business approved by stockholders is the best method to seek to maximize stakeholder value. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic options. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our business, we would be required to pay our outstanding obligations, as well as to make reasonable provisions for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the satisfaction of such obligations. In addition, we may be subject to litigation or other claims related to a liquidation and dissolution of our business. If a liquidation and dissolution are pursued, our board of directors, in consultation with its legal and financial advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock and other securities could lose all or a significant portion of their investment in the event of a liquidation and dissolution of the Company.** Risks Related to Our Business and Financial ConditionIf we continue to execute our current development strategy, we will need additional financing to fund our operations in the future. If we are unable to obtain additional financing on acceptable terms, we will need to curtail or cease our development plans and operations. As of December 31, ~~2023~~ **2024** , we had approximately $ ~~28~~ **17** . 7 million of available cash and cash equivalents. Our cash position is expected to be sufficient for at least the next 12 months, including the remaining costs of our ongoing Phase 2 clinical trial and other current development projects, from the date hereof as we continue to determine how to proceed with the current development programs. While we anticipate our current cash resources on hand will be sufficient to sustain operations and to fund our current, follow- on clinical ~~trial~~ **40trial** , we do not have sufficient capital to complete such planned follow- on or all necessary clinical trials in order to have a product approvable for commercial sale. As a result, we will need to raise additional capital and / or obtain a strategic partner to facilitate our development program and bringing a product to market. Our operating plans and capital requirements are subject to change based on how we determine to proceed with respect to our current development programs for Bryostatin- 1. We are currently reviewing our operating plans, and we will require additional capital in the future. Additional funds may be raised through the issuance of equity securities and / or debt financing, there being no assurance that any type of financing on terms acceptable to us will be available or otherwise occur. Debt financing must be repaid regardless of whether we generate revenues or cash flows from operations and may be secured by substantially all of our assets. Any equity financing or debt financing that requires the issuance of warrants or other equity securities to the lender would cause the percentage ownership by our current stockholders to be diluted, which dilution may be substantial. Also, any additional equity securities issued may have rights, preferences or privileges senior to those of existing stockholders. If such financing is not available when required or is

not available on acceptable terms, we may be required to reduce or eliminate certain product candidates and development activities, including those related to bryostatin, the " bryologs " or PUFAs, and it may ultimately require us to suspend or cease operations, which could cause investors to lose the entire amount of their investment. ~~42Our~~ -- **Our** ongoing viability as a company depends on our ability to successfully develop and commercialize our licensed technology. We are principally focused on developing a drug, Bryostatin- 1, for the treatment of AD and other diseases, which is still in the clinical testing stage and has not yet been fully developed. Our potential success is highly uncertain since Bryostatin- 1 did not achieve statistical significance on the primary endpoint, in its Phase 2 of development. On December 16, 2022, we announced that an extended confirmatory Phase 2 study of Bryostatin- 1 in moderate to severe AD (Study # 204) did not achieve statistical significance on the primary endpoint, which was change from baseline to week 13 in the SIB total score assessment obtained after completion of the second seven- dose course of treatment (week 28 of trial). Our other product candidates (use of Bryostatin- 1 to treat Niemann Pick Type- C and Fragile X Syndrome) are earlier in their development cycles. Bryostatin- 1 is also subject to regulatory approval. Our potential success depends upon our ability to raise more capital, complete development of and successfully commercialize Bryostatin- 1 in a timely manner for the treatment of AD or other diseases. If we are unable to develop Bryostatin- 1 for indications other than AD, the future growth of our business could be negatively impacted. We must develop Bryostatin- 1, successfully test it for safety and efficacy in the targeted patient population, and manufacture the finished dosage form on a commercial scale to meet regulatory standards and receive regulatory approvals. The development and commercialization process is both time- consuming and costly, and involves a high degree of business risk. Bryostatin- 1 is still at an early stage in its product development cycle, and any follow- on product candidates are still at the concept stage. The results of pre- clinical and clinical testing of our product candidates are uncertain and we cannot assure anybody that we will be able to obtain regulatory approvals of our product candidates. If obtained, regulatory approval may take longer or be more expensive than anticipated. Furthermore, even if regulatory approvals are obtained, our products may not perform as we expect and we may not be able to successfully and profitably produce and market any products. Delays in any part of the process or our inability to obtain regulatory approval of our products could adversely affect our future operating results by restricting (or even prohibiting) the introduction and sale of our products. ~~43If~~ **If** the CRE License were terminated, we may be required to cease operations. Our rights to develop, commercialize and sell certain of our proposed products, including Bryostatin- 1, is, in part, dependent upon the CRE License. CRE has the right to terminate this agreement after 30 days prior notice in certain circumstances, including if we were to materially breach any provisions of the agreement after a 60- day cure period for breaches that are capable of being cured, in the event of certain bankruptcy or insolvency proceedings. Additionally, the CRE License provides that the license may not be assigned, including by means of a change of control of the Company, or sublicensed without the consent of CRE. If the CRE License were terminated, we would lose rights to a substantial portion of the intellectual property currently being developed by us and no longer have the rights to develop, commercialize and sell some of our proposed products. As a result, we may be required to cease operations under such circumstance. ~~We~~ **41We** rely on independent third- party contract research organizations to perform clinical and non- clinical studies of our drug candidate and to perform other research and development services. The CRE License requires us to use CRE to provide research and development services and other scientific assistance and support services, including clinical trials, under certain conditions. The CRE License limits our ability to make certain decisions, including those relating to our drug candidate, without CRE' s consent. Under certain conditions, we may, however, also rely on independent third- party contract research organizations (" CROs "), to perform clinical and non- clinical studies of our drug candidate. We have previously entered into services agreements with WCT relating to our clinical trials of Bryostatin- 1. Many important aspects of the services that may be performed for us by CROs are out of our direct control. Nevertheless, we are responsible for ensuring that each clinical trial we sponsor is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. If there were to be any dispute or disruption in our relationship with such CROs, including WCT, the development of our drug candidate may be delayed. Moreover, in our regulatory submissions, we would expect to rely on the quality and validity of the clinical work performed by our CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be materially adversely impacted. We have relied on the representations and materials provided by CRE, including scientific, peer- reviewed and non- peer reviewed publications, abstracts, slides, internal documents, verbal communications, patents and related patent filings, with respect to the results of its research related to our proposed products. CRE began the development of the intellectual property that forms the basis for our proposed products in 1999. We have relied on the quality and validity of the research results obtained by CRE with respect to this intellectual property, and we have conducted limited verification of the raw preclinical and clinical data produced by CRE. No independent third- party has verified any such data. If any of CRE' s basic processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals, could be materially adversely impacted. ~~44We~~ **We** have a limited operating history upon which investors can evaluate our future prospects. Our drug product candidate, Bryostatin- 1, is in an early development stage and we are subject to all of the risks inherent in the establishment of a new business enterprise. While development of our product candidates was started in 1999 by CRE, we were incorporated on October 31, 2012 and on that same date entered into the Technology License and Services Agreement with CRE and NRV II, LLC for the continuing development and commercialization of our product candidates. Our proposed

products are currently in the research and development stage and we have not generated any revenues, nor do we expect our products to generate revenues for the near term, if ever. As a result, any investment in our securities must be evaluated in light of the potential problems, delays, uncertainties and complications encountered in connection with a newly established pharmaceutical development business. The risks include, but are not limited to, the possibilities that any or all of our potential products will be found to be unsafe, ineffective or, that the products once developed, although effective, are not economical to market; that our competitors hold proprietary rights that preclude us from marketing such products; that our competitors market a superior or equivalent product; or the failure to receive necessary regulatory clearances for our proposed products. To achieve profitable operations, we must successfully develop, obtain regulatory approval for, introduce and successfully market, sell or license at a profit, product candidates that are currently in the research and development phase. We only have one product candidate in clinical development, i. e., Bryostatin- 1 to treat AD. On December 16, 2022, we announced that an extended confirmatory Phase 2 study of Bryostatin- 1 in moderate to severe AD (Study # 204) did not achieve statistical significance on the primary endpoint, which was change from baseline to Week 13 in the SIB total score assessment obtained after completion of the second seven- dose course of treatment (week 28 of trial). We are currently evaluating the data and determining next steps with the development of Bryostatin- 1 for AD as well as for other potential indications. No assurance can be given that our research and development efforts will be successful, that required regulatory approvals will be obtained, that any of our candidates will be safe and effective, that any products, if developed and introduced, will be successfully marketed, sold or licensed or achieve market acceptance or that products will be marketed at prices necessary to generate profits. Failure to successfully develop, obtain regulatory approvals ~~for~~ **42for** , or introduce and market, sell or license our products would have material adverse effects on our business prospects, financial condition and results of operations. ~~45If~~ **If** we do not obtain the necessary regulatory approvals in the United States and / or other countries, we will not be able to sell our drug candidates. We cannot assure you that we will receive the approvals necessary to commercialize Bryostatin- 1, or any other potential drug candidates we acquire or attempt to develop in the future. We will need approval from the FDA to commercialize our drug candidates in the United States and approvals from similar regulatory authorities in foreign jurisdictions to commercialize our drug candidates in those jurisdictions. In order to obtain FDA approval of Bryostatin- 1 or any other drug candidate for the treatment of AD or any other indication, we must submit first an IND application and then an NDA to the FDA, demonstrating that the drug candidate is safe, pure and potent, and effective for its intended use. This demonstration requires significant research including completion of clinical trials. Satisfaction of the FDA' s regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the drug candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our drug candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the drug approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may prevent or delay commercialization of, and our ability to derive revenues from, our drug candidates and diminish any competitive advantages that we may otherwise believe that we hold. Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our applications. We may never obtain regulatory clearance for any of our drug candidates. Failure to obtain FDA approval of our drug candidates will leave us without a saleable product and therefore without any source of revenues. In addition, the FDA may require us to conduct additional clinical testing or to perform post- marketing studies, as a condition to granting marketing approval of a drug product or permit continued marketing, if previously approved. If conditional marketing approval is obtained, the results generated after approval could result in loss of marketing approval, changes in product labeling, and / or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post- market authority, including the explicit authority to require post- market studies and clinical trials, labeling changes based on new safety information and compliance with FDA- approved risk evaluation and mitigation strategies. The FDA' s exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post- approval regulatory requirements and potential restrictions on sales of approved drugs. In foreign jurisdictions, the regulatory approval processes generally include the same or similar risks as those associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize our drug candidates for sale either within or outside the United States. The commencement and completion of clinical trials can be delayed or prevented for a number of reasons. On December 16, 2022, we issued a press release announcing that the expanded confirmatory Phase 2 study of Bryostatin- 1 in moderate to severe AD did not achieve statistical significance on the primary endpoint. On March 7, 2023, we announced results of our analysis of secondary endpoints and post hoc analysis from our Phase 2 study of Bryostatin- 1. In the secondary endpoint analysis, changes from baseline at Weeks 9, 20, 24, 30, and 42 in the SIB (Severe Impairment Battery) total score were not statistically significant in the total patient population, and no pre- specified secondary endpoints were met with statistical significance in the low- to- moderately severe AD patient stratum. However, nearly all pre- specified secondary endpoints in the most advanced and severe AD (MMSE: 10- 14) patient population, with baseline MMSE- 2 (Mini- Mental State Examination, 2nd Edition) scores of 10- 14, were achieved with statistical significance ($p = < 0. 05$, 2- tailed). Data also showed statistical significance in exploratory secondary endpoints for the MMSE- 2 10- 14 stratum, and post hoc analysis was positive. **On July 19, 2023, we announced the commencement of Phase 1 clinical trials of Bryostatin- 1 in multiple sclerosis with the Cleveland Clinic. On December 20, 2024, we also disclosed the termination of our agreement with the Cleveland Clinic due to the slow pace of enrollment in the Phase 1 clinical trial.** We are planning to present the totality of the clinical data for Bryostatin- 1 upon trial completion. We are continuing to determine how to proceed with respect to our current development

programs for Bryostatin- 1. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Clinical trials can be delayed or prevented for a number of reasons, including: ● difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial; **43** ● delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, contract manufacturing organizations, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly; ~~46~~ ● failure of our third- party contractors, such as CROs and contract manufacturing organizations, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner; ● insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials; ● difficulties obtaining institutional review board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site; ● the FDA, EMA or other regulatory authority requiring alterations to any of our study designs, our pre- clinical strategy or our manufacturing plans; ● various challenges recruiting and enrolling subjects to participate in clinical trials, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, budgetary limitations, nature of trial protocol, change in the readiness of subjects to volunteer for a trial, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications; ● difficulties in maintaining contact with subjects after treatment, which results in incomplete data; ● governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and ● varying interpretations of data by the FDA and foreign regulatory agencies. In addition, Congress recently amended the FDCA to require sponsors of a Phase 3 clinical trial, or other " pivotal study " of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our product candidates has reached Phase 3 of clinical development, we must submit a diversity action plan to the FDA by the time we submit a Phase 3 trial, or pivotal study, protocol to the agency for review, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase 3 trial for our product candidates ~~or what specific information FDA will expect in such plans. However~~ , **but** initiation of such trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase 3 trial for our product candidates **. We** ~~, and we~~ may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan. Changes in regulatory requirements and guidance may also occur and we may need to significantly amend clinical trial protocols or submit new clinical trial protocols with appropriate regulatory authorities to reflect these changes. Amendments may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs or ethics committees for re- examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB or ethics committee overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us, due to a number of factors, including: ● failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; ● inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities; ● unforeseen issues, including unexpected serious adverse events associated with a product candidate, or lack of effectiveness or any determination that a clinical trial presents unacceptable health risks; ● lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; ~~and~~ **and44** ● upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates. ~~47Moreover~~ -- **Moreover** , principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of one or more of our product candidates. If we do not succeed in conducting and managing our preclinical development activities or clinical trials, or in obtaining regulatory approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which could have a material adverse effect on our business, prospects, financial condition and results of operations. Even if regulatory approvals are obtained for our product candidates, we will be subject to ongoing government regulation. If we fail to comply with applicable current and future laws and government regulations, it could delay or prevent the promotion, marketing or sale of our products. Even if marketing approval is obtained, a regulatory authority may still impose significant restrictions on a product' s indications, conditions for use, distribution or marketing or impose ongoing requirements for potentially costly post- market surveillance, post- approval studies or clinical trials, all of which may result in significant expense and limit our ability to commercialize our products. Our products will also be subject to ongoing requirements governing the labeling, packaging, storage, advertising, distribution, promotion, recordkeeping and submission of safety and other post- market information, including adverse events, and any changes to the approved product, product labeling or manufacturing process. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practice, or cGMP, requirements and other regulations. If we, our drug products or the manufacturing facilities for our drug products fail to comply with applicable regulatory requirements, a regulatory agency may: ● issue warning letters or untitled letters; ● seek an injunction or impose civil or criminal penalties or monetary fines; ● suspend or withdraw marketing approval; ● suspend any ongoing clinical trials; ● refuse to approve pending applications or supplements to applications; ● suspend or impose restrictions on operations, including costly new manufacturing requirements; ● seize or detain products, refuse to permit the import or export of products or request that we initiate a product recall; or ●

refuse to allow us to enter into supply contracts, including government contracts. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, and compliance with such regulation may be expensive and consume substantial financial and management resources. If we or any future marketing collaborators or contract manufacturers are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or are not able to maintain regulatory compliance, it could delay or prevent the promotion, marketing or sale of our products, which would adversely affect our business and results of operations. ~~48Data~~ **45Data** from our Bryostatin- 1 Phase 2 clinical trial, from our confirmatory Phase 2 clinical trial and our expanded Phase 2 clinical trial may be subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share the Company' s views of the data. On May 1, 2017, we reported topline results from our Phase 2 clinical trial of Bryostatin- 1 for the treatment of moderate to severe AD. In January 2018, we reported the secondary analysis of data from the Phase 2 clinical trial. Further, on September 9, 2019, we reported topline results from our confirmatory Phase 2 clinical trial. On January 22, 2020, we reported additional analysis in connection with the confirmatory Phase 2 clinical trial. On December 16, 2022, we announced that an extended confirmatory Phase 2 study of Bryostatin- 1 in moderate to severe AD (Study # 204) did not achieve statistical significance on the primary endpoint, which was change from baseline to Week 13 in the SIB total score assessment obtained after completion of the second seven- dose course of treatment (week 28 of trial). **On July 19, 2023, we announced the commencement of Phase 1 clinical trials of Bryostatin- 1 in multiple sclerosis with the Cleveland Clinic. On December 20, 2024, we also disclosed the termination of our agreement with the Cleveland Clinic due to the slow pace of enrollment in the Phase 1 clinical trial.** We are currently evaluating the data and determining next steps with the development of Bryostatin- 1 for AD as well as for other potential indications. Further analyses of the Phase 2 data and confirmatory Phase 2 data may lead to different interpretations of the respective data than the analyses conducted to date and / or may identify important implications of the Phase 2 data, Phase 2 confirmatory data and Phase 2 extended confirmatory trial data, respectively, that are not currently known. Topline data are subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, any topline data should be viewed with caution until the final data are available. In addition, clinical trial data are subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share our views of the data. There can be no assurance that the clinical program for Bryostatin- 1 will be successful in demonstrating safety and / or efficacy that we will not encounter problems or delays in clinical development, or that Bryostatin- 1 will ever receive regulatory approval or be successfully commercialized. We have not generated any revenues since our inception and we do not expect to generate revenue for the foreseeable future. If we do not generate revenues and achieve and sustain profitability, we will likely need to curtail or cease our development plans and operations. Our ability to generate revenues depends upon many factors, including our ability to complete our currently planned clinical study and development of our proposed products, our ability to obtain necessary regulatory approvals for our proposed products and our ability to successfully commercialize market and sell our products. We have not generated any revenues since we began operations on October 31, 2012. We expect to incur significant operating losses over the next several years. If we do not generate revenues, do not achieve profitability and do not have other sources of financing for our business, we will likely need to curtail or cease our development plans and operations, which could cause investors to lose the entire amount of their investment. Our commercial success will depend, in part, on our ability, and the ability of our licensors, to obtain and maintain patent protection. Our licensors' failure to obtain and maintain patent protection for our products may have a material adverse effect on our business. Pursuant to the CRE License, we have obtained rights to certain patents owned by CRE or licensed to NRV II, LLC by CRE as of or subsequent to October 31, 2012. In the future, we may seek rights from third parties to other patents or patent applications. Our success will depend, in part, on our ability and the ability of our licensors to maintain and / or obtain and enforce patent protection for our proposed products and to preserve our trade secrets, and to operate without infringing upon the proprietary rights of third parties. Patent positions in the field of biotechnology and pharmaceuticals are generally highly uncertain and involve complex legal and scientific questions. We cannot be certain that we or our licensors were the first inventors of inventions covered by our licensed patents or that we or they were the first to file. Accordingly, the patents licensed to us may not be valid or afford us protection against competitors with similar technology. The failure to maintain and / or obtain patent protection on the technologies underlying our proposed products may have material adverse effects on our competitive position and business prospects. ~~49Our~~ -- **Our** licensed patented technologies may infringe on other patents, which may expose us to costly litigation. It is possible that our licensed patented technologies may infringe on patents or other rights owned by others. We may have to alter our products or processes, pay additional licensing fees, pay to defend an infringement action or challenge the validity of the patents in court or cease activities altogether because of patent rights of third parties, thereby causing additional unexpected costs and delays to us. Patent litigation is costly and time consuming, and we may not have sufficient resources to pay for such litigation. Pursuant to the CRE License, CRE has the exclusive right (but not the obligation) to apply for, file, prosecute or maintain patents and patent applications ~~for~~ **46for** our licensed technologies. However, in order to maintain our rights to use our licensed technologies, we must reimburse CRE for all of the attorney' s fees and other costs and expenses related to any of the foregoing. For additional information regarding the CRE License, see " **Item 1.** Business — Intellectual Property — Technology License and Services Agreement. " If the patents licensed to us are determined to infringe a patent owned by a third party and we do not obtain a license under such third- party patents, or if we are found liable for infringement or are not able to have such third- party patents declared invalid, we may be liable for significant money damages, we may encounter significant delays in bringing products to market or we may be precluded from participating in the manufacture, use or sale of products or methods of treatment requiring such licenses. We are dependent on Dr. Alan Tuchman, M. D., our Chief Executive Officer, for the successful execution of our business plan. The loss of Dr. Tuchman or other key members of our management team could have a material adverse effect on our business prospects. We are highly dependent on Dr. Tuchman, our Chief Executive Officer. We are dependent on Dr. Tuchman' s and

our directors' networks of contacts and experience to recruit key talent to the Company. We do not have key- man insurance on any of our officers. Loss of the services of Dr. Tuchman or other key members of our management team, or of our board of directors (the " Board ") ability to identify and hire key talent, could have a material adverse effect on our business prospects, financial condition and results of operations. We may not be able to protect our trade secrets and other unpatented proprietary technologies, which could give our competitors an advantage over us. In addition to our reliance on patents and pending patents owned by CRE, we rely upon trade secrets and other unpatented proprietary technologies. We may not be able to adequately protect our rights with regard to such unpatented proprietary technologies or competitors may independently develop substantially equivalent technologies. We seek to protect trade secrets and proprietary knowledge, in part through confidentiality agreements with our employees, consultants, advisors and collaborators. Nevertheless, these agreements may not effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of such information and, as a result, our competitors could gain a competitive advantage over us. If we are unable to hire additional qualified personnel, our business prospects may suffer. Our success and achievement of our business plans depend upon our ability to recruit, hire, train and retain other highly qualified technical and managerial personnel. Competition for qualified employees among pharmaceutical and biotechnology companies is intense, and the loss of any of such persons, or an inability to attract, retain and motivate any additional highly skilled employees required for the implementation of our business plans and activities could have a material adverse effect on us. Our inability to attract and retain the necessary technical and managerial personnel and consultants and scientific and / or regulatory consultants and advisors could have a material adverse effect on our business prospects, financial condition and results of operations. We may not be able to in- license or acquire new development- stage products or technologies. Our product commercialization strategy relies, to some extent, on our ability to in- license or acquire product formulation techniques, new chemical entities, or related know- how that has proprietary protection. If resources permit, we may also seek to acquire, by license or otherwise, other development stage products that are consistent with our product portfolio objectives and commercialization strategy. The acquisition of products requires the identification of appropriate candidates, negotiation of terms of acquisition, and financing for the acquisition and integration of the candidates into our portfolio. Failure to accomplish any of these tasks may diminish our growth rate and adversely alter our competitive position. ~~50We~~ **We** are partly dependent upon the NCI to supply bryostatin for our clinical trials. CRE has entered into a material transfer agreement with the NCI, pursuant to which the NCI has agreed to supply bryostatin required to synthesize Bryostatin- 1 for our pre- clinical research and clinical trials. This agreement does not provide for a sufficient amount of bryostatin to support the completion of our clinical trials that we are required to conduct in order to seek FDA approval of Bryostatin- 1 for the treatment of AD. Therefore, CRE or we will have to enter into one or more subsequent agreements with the NCI for the supply of additional amounts of bryostatin. If CRE or we are unable to secure such additional agreements or if the NCI otherwise discontinues for any reason supplying us with bryostatin, then we would have to either secure another source of bryostatin or discontinue our efforts to develop and commercialize Bryostatin- 1 for the treatment of AD. In the interest of mitigating this risk, we have entered ~~into~~ **47into** license agreements with Stanford for the development of bryostatin structural derivatives known as " bryologs " and an accelerated synthesis of Bryostatin- 1 as alternative potential sources of bryostatin. In addition, we entered into the Supply Agreement with BryoLogyx on June 9, 2020, pursuant to which BryoLogyx agreed to serve as our exclusive supplier of synthetic bryostatin. There can be no assurance that we will be able to secure future bryostatin supplies from any source on commercially reasonable terms, if at all. We expect to rely on third parties to manufacture our proposed products and, as a result, we may not be able to control our product development or commercialization. We currently do not have an FDA approved manufacturing facility. We expect to rely on contract manufacturers to produce quantities of products and substances necessary for product commercialization. See also the risk factor above captioned " We are partly dependent upon the NCI to supply bryostatin for our clinical trials. " Contract manufacturers that we use must adhere to cGMP enforced by the FDA through its facilities inspection program. If the facilities of such manufacturers cannot pass a pre- approval plant inspection, the FDA pre- market approval of our products will not be granted. As a result: ● there are a limited number of manufacturers that could produce the products for us and we may not be able to identify and enter into acceptable agreements with any manufacturers; ● the products may not be produced at costs or in quantities necessary to make them commercially viable; ● the quality of the products may not be acceptable to us and / or regulatory authorities; ● our manufacturing partners may go out of business or file for bankruptcy; ● our manufacturing partners may decide not to manufacture our products for us; ● our manufacturing partners could fail to manufacture to our specifications; ● there could be delays in the delivery of quantities needed; ● we could be unable to fulfill our commercial needs in the event we obtain regulatory approvals and there is strong market demand; or ● ongoing inspections by the FDA or other regulatory authorities may result in suspensions, seizures, recalls, fines, injunctions, revocations and / or criminal prosecutions. If we are unable to engage contract manufacturers or suppliers to manufacture or package our products, or if we are unable to contract for a sufficient supply of required products and substances on acceptable terms, or if we encounter delays or difficulties in our relationships with these manufacturers, or with a regulatory agency, then the submission of products for regulatory approval and subsequent sales of such products would be delayed. Any such delay may have a material adverse effect on our business prospects, financial condition and results of operations. ~~51We~~ **We** may rely on third parties for marketing and sales and our revenue prospects may depend on their efforts. We currently have no experience in sales, marketing or distribution. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products. As a result, if our product development is successful, our future success will likely depend, in part, on our ability to enter into and maintain collaborative relationships with one or more third parties for sales, marketing or distribution, on the collaborator' s strategic interest in the products we have under development and on such collaborator' s ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products as appropriate. However, we may not be able to establish or maintain such collaborative arrangements or, if we are able to do so, they may not have effective sales forces. To the extent that we decide not

to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in- house marketing and sales force with technical expertise. ~~To~~ **48To** the extent that we depend on third parties for marketing and distribution, any revenues received by us will depend upon the efforts of such third parties, which may not be successful. If our products are not accepted by patients, the medical community or health insurance companies, our business prospects will suffer. Commercial sales of any products we successfully develop will substantially depend upon the products' efficacy and on their acceptance by patients, the medical community, providers of comprehensive healthcare insurance, healthcare benefit plan managers, the Centers for Medicare and Medicaid Services (" CMS ") (which is the U. S. federal agency which administers Medicare, Medicaid and the State Children' s Health Insurance Program), and other organizations. Widespread acceptance of our products will require educating patients, the medical community and third- party payors of medical treatments as to the benefits and reliability of the products. Our proposed products may not be accepted, and, even if they are accepted, we are unable to estimate the length of time it would take to gain such acceptance. The branded prescription segment of the pharmaceutical industry in which we operate is competitive, and we are particularly subject to the risks of such competition. The branded prescription segment of the pharmaceutical industry in which we operate is competitive, in part because the products that are sold require extensive sales and marketing resources invested in their commercialization. The increasing cost of prescription pharmaceuticals has caused providers of comprehensive healthcare insurance, healthcare benefit plan managers, CMS, as well as other organizations, collectively known as third- party payors, to tightly control and dictate their drug formulary plans to control the costs associated with the use of prescription pharmaceutical products by enrollees in these plans. Our ability to gain formulary access to drug plans supported by these third- party payors is substantially dependent on the differentiated patient benefit that our proposed products can provide, compared closely to similar products claiming the same benefits or advantages. We may not be able to differentiate our proposed products from those of our competitors, successfully develop or introduce new products that are less costly or offer better performance than those of our competitors, or offer purchasers of our proposed products payment and other commercial terms as favorable as those offered by our competitors. We expect that some of our proposed products, even if successfully developed and commercialized, will eventually face competition from a significant number of biotechnology or large pharmaceutical companies. Because most of our competitors have substantially greater financial and other resources than we have, we are particularly subject to the risks inherent in competing with them. The effects of this competition could materially adversely affect our business prospects, financial condition and results of operations. We compete with many companies, research institutes, hospitals, governments and universities that are working to develop products and processes to treat or diagnose AD. We believe that others are doing research on Fragile X syndrome and Niemann Pick disease. Many of these entities have substantially greater financial, technical, manufacturing, marketing, distribution and other resources than we do. However, there has been a limited number of new product introductions in the last 20 years for the treatment of AD symptoms in patients who begin exhibiting the memory and cognitive disorders associated with the disease. All of the products introduced to date for the treatment of AD have yielded negative or marginal results with little effect on the progression of AD and no improvement in the memory or cognitive performance of the patients receiving these therapies. The absolute determination of AD in patients is currently achieved only upon autopsy. We believe we are the only company currently pursuing PKC ε activation as a mechanism to treat AD and neurodegenerative diseases. Although we believe that we have no direct competitors working in this same field on product candidates using the same mechanism of action, we cannot provide assurance that our competitors will not discover compounds or processes that may be competitive with our products and introduce such products or processes before us. ~~52We~~ **We** are developing our product candidates to address unmet medical needs in the treatment of AD and other neurodegenerative diseases. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop our product candidates, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position. ~~Our~~ **49Our** business will expose us to potential product liability risks, which could result in significant product liability exposure. Our business will expose us to potential product liability risks that are inherent in the testing, designing, manufacturing and marketing of human therapeutic products. Product liability insurance in the pharmaceutical industry is generally expensive, and we may not be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities, if at all. A successful products liability claim brought against us could have a material adverse effect on our business prospects, financial condition and results of operations. A successful clinical trial liability claim against us could have a material adverse effect on our financial condition even with such insurance coverage. Our business will expose us to potential liability that results from risks associated with conducting clinical trials of our product candidates. Although we have procured clinical trial product liability insurance coverage for our Bryostatin- 1 product candidate with coverages and deductibles we believe are adequate, there is no guarantee that our coverage will be adequate to satisfy any liability we may incur. We do not currently have insurance with respect to any other drug product. A successful clinical trial liability claim brought against us could have a material adverse effect on our business prospects, financial condition and results of operations even if we successfully obtain clinical trial insurance. A successful liability claim against us could have a material adverse effect on our financial condition. Our business and actions can expose us to potential liability risks that are inherent in business, generally, and in the pharmaceutical industry, specifically. While we maintain commercial general liability insurance with coverages and deductibles we believe are adequate, there is no guarantee that our coverage will be adequate to satisfy any liability we may incur. A successful liability claim brought against us could have a material adverse effect on our business prospects, financial condition

and results of operations. ~~53Reforms~~ -- **Reforms** in the healthcare industry and the uncertainty associated with pharmaceutical and laboratory test pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for our products. ~~Public~~ **All aspects of our business, including research** and **development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable U. S. federal and state laws and agency regulation, as well as foreign laws and regulations, could have a materially negative impact on our business. In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates or any of our potential future product candidates, restrict or regulate post- approval activities, or affect our ability to profitably sell any product candidates for which we obtain marketing approval. Increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. We cannot be sure whether additional legislative changes will be enacted, or whether any of the FDA' s regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. Our ability to commercialize any product candidates successfully also will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from governmental authorities or health care programs,** private ~~entities~~ **health plans, and other organizations. Even if we succeed in bringing one or more products to the market, such products may not be considered medically necessary or cost- effective, and the amount reimbursed for the products may be insufficient to allow us to sell them on a competitive basis. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. For examples, see the section above titled " Governmental Regulation and Product Approval – Healthcare Reform. " Increasingly, third- party payors** are ~~seeking ways to reduce~~ **challenging the prices charged** ~~or~~ **for medical products and requiring that** ~~contain increasing healthcare costs. All generic~~ pharmaceutical ~~manufacturers whose~~ **companies provide them with predetermined discounts from list prices. Novel medical products, if covered at all, may be subject to enhanced utilization management controls designed to ensure that the** products are ~~covered~~ **used only when medically necessary. Such utilization management controls may discourage the prescription or use of a medical product** by **increasing** ~~the Medicaid program are required to rebate to each state a percentage of their~~ -- **the** " **administrative burden associated with its prescription or creating** ~~average~~ **coverage** ~~manufacturer~~ **uncertainties for prescribers and patients. We cannot be sure that reimbursement will be available for any product candidate we may be able to commercialize and, if reimbursement is available, that the level of reimbursement 50will be adequate. Reimbursement may impact the demand for, or the** price ~~"~~ **of, any product candidate** for ~~the~~ **which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any** ~~products~~ **product candidate** ~~in question. The extension of prescription drug coverage to all Medicare recipients was approved by Congress several years ago. Under the IRA, CMS will start negotiating drug prices annually, beginning with payment year 2026,~~ for ~~a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. In addition, President Biden' s Executive Order 14087, issued October 2022, called for CMS to prepare and submit a report to the White House on potential payment and delivery modes that would complement to IRA, lower drug costs, and promote access to innovative drugs. In February 2023, CMS published its report~~ which **we obtain marketing approval** ~~described three potential models focusing on affordability, accessibility and feasibility of implementation for further testing by the CMS Innovation Center. As of February 2024, the CMS Innovation Center continues to test the proposed models and has started to roll out plans for access model testing of certain product types (e. g., cell and gene therapies) by states and manufacturers. Numerous other proposals to curb rising pharmaceutical prices have also been enacted by or otherwise introduced or proposed in Congress and in many state legislatures~~. We cannot predict the nature of ~~the~~ **any** measures that may be adopted **by governmental authorities or private payors** or their effect on our competitive position. Our ability to market our products depends, in part, on reimbursement levels for them and related treatment established by healthcare providers, private health insurers and other organizations, including health maintenance organizations and managed care organizations. In the event that governmental authorities enact additional legislation or adopt regulations that affect third party coverage and reimbursement, demand for our products may be reduced, which may materially adversely affect our business prospects, financial condition and results of operations. Disruptions in federal government operations or extended government shutdowns may negatively impact our business. Any disruption in federal government operations could have a material adverse effect on our business, results of operations and financial condition. An extended federal government shutdown resulting from failure to pass budget appropriations, to adopt continuing funding resolutions or to raise the debt ceiling, for example, or any other budgetary decisions limiting or delaying federal government spending, could negatively impact our business. In particular, disruptions in federal government operations may negatively impact regulatory approvals and guidance that are important to our operations, and create uncertainty about the pace of upcoming healthcare regulatory developments. Our business and operations would suffer in the event of computer system failures. Despite the implementation of security measures, our internal computer systems and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Like other companies, we may from time to time experience threats to our data and systems, including malware and computer virus attacks, unauthorized access, systems failures and disruptions. See " We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of

confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure ” below for more information regarding risks related to possible cyberattacks. If a disruption event were to occur and cause interruptions in our operations, it could result in a material 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 the further development of Bryostatin- 1 could be delayed.

~~54Consolidation~~ -- **Consolidation** in the pharmaceutical industry could materially affect our ability to operate as an independent entity. The pressure to grow revenues while containing the escalating costs of basic research and development has resulted in an increase in mergers and acquisitions in our industry. More consolidation in the pharmaceutical industry is expected over the next five years. We could become an acquisition target by a larger competitor and, as a consequence, suffer serious disruptions to our business model or even lose control of our ability to operate as an independent entity. Such events could have a material adverse effect on our product development efforts or the commercialization of our proposed products. We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the military conflict between Russia and Ukraine and armed conflicts between Israel and Hamas. Our business, financial condition and results of operations may be materially and adversely affected by any negative impact on the global economy and capital markets resulting from the conflicts in Ukraine, the Gaza Strip or any other geopolitical tensions. U. S. and global markets have experienced volatility and disruption following the escalation of geopolitical tensions, including the military conflict between Russia and Ukraine, armed conflicts between Israel and Hamas and the related Red Sea crisis, where Houthi forces based in Yemen have been attacking freighters. Although the length and impact of the ongoing conflicts is highly unpredictable, such conflicts could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions. We are continuing to monitor the situations in Ukraine, the Gaza Strip and globally and ~~assessing~~ **51assessing** their potential impacts on our business. In addition, sanctions on Russia and hostilities involving Israel could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. Any of the above **-** mentioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military actions, sanctions and resulting market disruptions are impossible to predict, but could be substantial ~~. The impact of the COVID- 19 pandemic, the shift to a COVID- 19 endemic approach and related risks could materially affect our results of operations, financial position and / or liquidity. The COVID- 19 pandemic resulted in a global slowdown of economic activity and disruption of normal business travel and working habits. While we are shifting to a COVID- 19 endemic approach, there is still uncertainty about the impact of COVID- 19 variants in the long- term. The COVID- 19 pandemic may have impacted our results of operations, and a reversion to the COVID- 19 restrictions could have a significant effect on our future business, results of operations and financial performance. The pandemic initially resulted in a sharp contraction in the global economy, tightening liquidity and increasing volatility and uncertainty in the capital markets. Coincident global mitigation responses stabilized markets and stimulated economic recovery. Continued macroeconomic volatility may persist affecting our businesses and related market opportunities. The impact of an ongoing pandemic on the financial markets may also adversely affect our ability to fund through public or private equity offerings, debt financings, and through other means at acceptable terms~~ . Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act could materially and adversely affect us. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the Dodd- Frank Act and are required to prepare our financial statements according to the rules and regulations required by the SEC. In addition, the Exchange Act requires that we file annual, quarterly and current reports. Our failure to prepare and disclose this information in a timely manner or to otherwise comply with applicable law could subject us to penalties under federal securities laws, expose us to lawsuits and restrict our ability to access financing. In addition, the Sarbanes- Oxley Act requires that, among other things, that we establish and maintain effective internal controls and procedures for financial reporting and disclosure purposes. Internal control over financial reporting is complex and may be revised over time to adapt to changes in our business, or changes in applicable accounting rules. We cannot assure you that our internal control over financial reporting will be effective in the future or that a material weakness will not be discovered with respect to a prior period for which we had previously believed that internal controls were effective. ~~55We~~ **We have** identified material weaknesses in our internal control over financial reporting. Matters affecting our internal controls may cause us to be unable to report our financial information on a timely basis or may cause us to restate previously issued financial information, and thereby subject us to adverse regulatory consequences, including sanctions or investigations by the SEC, or violations of applicable stock exchange listing rules. There could also be a negative reaction in the financial markets due to a loss of investor confidence in our company and the reliability of our financial statements. Confidence in the reliability of our financial statements is also likely to suffer if we or our independent registered public accounting firm reports a material weakness in our internal control over financial reporting. This could have a material and adverse effect on us by, for example, leading to a decline in our share price and impairing our ability to raise additional capital. Further, there are inherent limitations to the effectiveness of any system of controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. We could face additional litigation exposure and a greater likelihood of an SEC enforcement or other regulatory action if further restatements were to occur or other accounting- related problems emerge. We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure. We rely on information technology systems that we or our third- party providers operate to process, transmit and store electronic information in our day- to- day operations. In connection with our product discovery efforts, we may collect and use a variety of

personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial- of- service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e. g., state breach notification laws), federal (e. g., HIPAA, as amended by HITECH), and international law (e. g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business. ~~In~~ **52In** addition, the computer systems of various third parties on which we rely, and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third- party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third- party providers could have difficulty preventing, detecting and controlling such cyber- attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. ~~56Our~~ -- **Our** failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and / or adverse publicity and could negatively affect our operating results and business. We are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and there has been an increasing focus on privacy and data security issues with the potential to affect our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal consumer protection laws govern the collection, use, disclosure and protection of health- related and other personal data. Many U. S. states are also enacting consumer privacy statutes to enhance protections for personal data and to provide residents with more choices concerning their data collected by businesses, increasing compliance complexity and increasing risks of failures to comply. In addition, foreign data protection, privacy, and other laws and regulations can be more restrictive than those in the United States. Data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and / or processed within that country. We could be subject to audits in Europe and around the world, particularly in the areas of consumer and data protection, as we operate our business. Legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change our business practices. These changes or increased costs could negatively impact our business and results of operations in material ways. For example, the General Data Protection Regulation (" GDPR ") imposes requirements in the European Economic Area relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third- party processors. GDPR also imposes restrictions on the transfer of personal data from the EEA to third countries like the United States. Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we cannot be assured of compliance with the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. Furthermore, the number of government investigations related to data security incidents and privacy violations continues to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and reputation. Failure to comply with data protection laws may expose us to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, potential significant fines and penalties if we are found to be non- compliant, and / or adverse publicity, any of which could negatively affect our operating results and business. ~~Increasing scrutiny and evolving expectations from customers, regulators, investors, and other stakeholders with respect to our environmental, social and governance (ESG) practices may impose additional costs on us or expose us to new or additional risks. Companies are facing increasing scrutiny from customers, regulators, investors, and other stakeholders related to their ESG practices and disclosure. Investor advocacy groups, investment funds and influential investors are also increasingly focused on these practices, especially as they relate to the environment, climate change, health and safety, supply chain management, diversity, labor conditions and human rights, both in our own operations and in our supply chain. Increased ESG- related compliance costs for the Company as well as among our suppliers, vendors and various other parties within our supply chain could result in material increases to our overall operational costs. Failure to adapt to or~~

~~comply with regulatory requirements or investor or stakeholder expectations and standards could negatively impact our reputation, ability to do business with certain partners, access to capital, and our stock price. 57We are subject to risks related to corporate and social responsibility and reputation. Many factors influence our reputation including the perception of us held by our customers, suppliers, partners, shareholders, other key stakeholders, and the communities in which we operate. We face increasing scrutiny related to environmental, social and governance activities. We risk damage to our reputation if we fail to act responsibly in a number of areas, such as diversity and inclusion, environmental stewardship, sustainability, supply chain management, climate change, workplace conduct, and human rights. Any harm to our reputation could impact employee engagement and retention, our corporate culture, and the willingness of customers, suppliers, and partners to do business with us, which could have a material adverse effect on our business, results of operations and cash flows. Further, despite our policies to the contrary, we may not be able to control the conduct of every individual actor, and our employees and personnel may violate environmental, social or governance standards or engage in other unethical conduct. These acts, or any accusation of such conduct, even if proven to be false, could adversely impact the reputation of our business.~~ Our employees, independent contractors, principal investigators, contract research organizations, consultants or vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, principal investigators, contract research organizations, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; manufacturing standards; federal and state healthcare fraud and abuse laws and regulations; or laws that require the true, complete and accurate reporting of financial information or data. In addition, sales, ~~marketing~~ **53marketing** and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our nonclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished potential profits and future earnings, and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations or prospects. Risks Relating to our Common Stock and the Securities MarketThe market price of our common stock has been volatile. The market price of our Common Stock has fluctuated substantially due to a number of factors, many of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your investment in our Common Stock since you might be unable to sell your shares at or above the price you paid. Factors that could cause fluctuations in the trading price of our common stock include the following: ● price and volume fluctuations in the overall stock market from time to time; ● volatility in the trading prices and trading volumes of stocks in our industry; ● changes in operating performance and stock market valuations of other companies generally, or those in our industry in particular; ● sales of shares of our Common Stock by us or our stockholders; ~~58~~ ● failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company or our failure to meet these estimates or the expectations of investors; ● the financial projections we may provide to the public, any changes in those projections or our failure to meet those projections; ● announcements by us or our competitors of new offerings or features; ● the public' s reaction to our press releases, other public announcements and filings with the SEC; ● rumors and market speculation involving us or other companies in our industry; ● actual or anticipated changes in our results of operations or fluctuations in our results of operations; ● actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally; ● litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors; ● developments or disputes concerning our intellectual property or other proprietary rights; **54** ● announced or completed acquisitions of businesses, services or technologies by us or our competitors; ● new laws or regulations or new interpretations of existing laws or regulations applicable to our business; ● changes in accounting standards, policies, guidelines, interpretations or principles; ● any significant change in our management; and ● general economic conditions and slow or negative growth of our markets. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company' s securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management' s attention and resources. If we fail to meet the continued listing standards of Nasdaq, our common stock may be delisted, which may adversely affect the market price and liquidity of our common stock. Our common stock is currently traded on the Nasdaq. Nasdaq requires us to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order to continue the listing of our common stock, including that we maintain a minimum closing bid price of $ 1. 00 per share (the " Minimum Bid Price Requirement "). ~~On April 24, 2023, we received written notice from the Nasdaq Listing Qualifications Department (the " Staff ") notifying us that for the preceding 30 consecutive business days, our Common Stock did not maintain a minimum closing bid price of $ 1. 00 per share as required by the Minimum Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we received an initial grace period of 180 calendar days, or until October~~

~~23, 2023, to regain compliance with the Minimum Bid Price Requirement (the " Initial Compliance Period "). We did not regain compliance with the Minimum Bid Price Requirement within the Initial Compliance Period, and on October 24, 2023, we received a second written notice from the Staff granting us an additional grace period of 180 calendar days, or until April 22, 2024, to regain compliance with the Minimum Bid Price Requirement (the " Additional Compliance Period "). Compliance can be achieved automatically and without further action if the closing bid price of our Common Stock is at or above $ 1. 00 for a minimum of 10 consecutive business days at any time during the Additional Compliance Period, in which case the Staff will notify us of our compliance and the matter will be closed. 59If, however, we do not achieve compliance with the Minimum Bid Price Requirement within the Additional Compliance Period, the Staff will notify us that our Common Stock is subject to delisting. At such time, we may appeal the delisting determination to a panel, but there can be no guarantee that such an appeal would be successful.~~ There can be no assurance that we will ~~be able to regain~~ **remain in** compliance with the Minimum Bid Price Requirement ~~during the Additional Compliance Period~~ or that we will be able to maintain compliance with the other requirements for continued listing of our common stock on Nasdaq. If our common stock is delisted and we are unable to list our common stock on another U. S. national securities exchange, we expect our securities would be quoted on an over- the- counter market. If this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock and reduced liquidity for the trading of our securities. Furthermore, if our common stock were delisted it could adversely affect our ability to obtain financing for the continuation of our operations and / or result in the loss of confidence by investors, customers, suppliers and employees. ~~The requirement that we redeem the Series B Preferred Stock in cash could adversely affect our business plan, liquidity, financial condition, and results of operations. If not converted, we are required to redeem some or all of the outstanding shares of Series B Preferred Stock for cash under certain circumstances. These obligations could have important consequences on our business. In particular, they could: ● limit our flexibility in planning for, or reacting to, changes in our businesses and the industries in which we operate; ● increase our vulnerability to general adverse economic and industry conditions; and ● place us at a competitive disadvantage compared to our competitors. As of the date of filing this Annual Report on Form 10- K, the trading price of our Common Stock is below the " floor price " set by the certificate of designations for the Series B Preferred Stock (as amended, the " Certificate of Designations ") for purposes of calculating amortization payments thereunder, and as a result we are limited in our ability to make monthly amortization payments in stock. No assurances can be given that we will be successful in making the required payments to the holders of the Series B Preferred Stock or that we will be able to comply with the financial or other covenants contained in the Certificate of Designations. If we are unable to make the required cash payments or otherwise comply with the Certificate of Designations: ● dividends will accrue on the Series B Preferred Stock at 15 % per annum; ● the holders of the Series B Preferred Stock could foreclose against our assets; and / or ● we could be forced into bankruptcy or liquidation. The terms of the Series B Preferred Stock could limit our growth and our ability to finance our operations, fund our capital needs, respond to changing conditions and engage in other business activities that may be in our best interests. The Certificate of Designations contains a number of affirmative and negative covenants regarding matters such as the payment of dividends, maintenance of our properties and assets, transactions with affiliates, and our ability to issue other indebtedness. Our ability to comply with these covenants may be adversely affected by events beyond our control, and we cannot assure you that we can maintain compliance with these covenants. The financial covenants could limit our ability to make needed expenditures or otherwise conduct necessary or desirable business activities.~~ A significant number of our shares of Common Stock are or will be eligible for future sale, which may cause the market price for our Common Stock to decline. As of December 31, ~~2023~~ **2024** , we had an aggregate of ~~24~~ **1** , ~~089~~ **357** , ~~646~~ **165** shares of Common Stock outstanding. Except for ~~192~~ **7** , ~~015~~ **681** shares, all of those shares are freely tradable without restriction or registration under the Securities Act of 1933, as amended (the " Securities Act "). ~~60On January 21~~ **On September 10** , ~~2021~~ **2024** , we entered into **a** Securities Purchase ~~Agreements~~ **Agreement** (the " ~~January~~ **Series C** Purchase Agreement ") with certain accredited investors (the " ~~January Purchasers ") to issue (a) an aggregate of 2, 333, 884 shares of our Common Stock and / or pre- funded warrants to purchase shares of our Common Stock at an exercise price of $ 0. 01 per share (the " January Pre- Funded Warrants "), (b)~~ Series **C** ~~E warrants to purchase 2, 333, 908 shares of Common Stock, with an exercise price of $ 8. 51 per share (subject to adjustment), for a period of twelve months from the date of an effective registration statement (the " Series E Warrants ") and (c) Series F warrants to purchase up to an aggregate of 2, 333, 908 shares of Common stock, with an exercise price of $ 6. 90 per share (subject to adjustment), for a period of five years from the date of issuance (the " Series F Warrants " and together with the Series E Warrants, the " January Warrants ") at a combined purchase price of $ 6. 00 per share of Common Stock and January Warrants (the " January Offering "). In connection with the January Purchase Agreement, we entered into a Registration Rights Agreement with the Purchasers (the " January Registration Rights Agreement ") on January 21, 2021. Under the terms of the January Registration Rights Agreement, we filed a registration statement on Form S- 1 to register the resale of the shares underlying the securities sold in the January Offering, which registration statement was declared effective by the SEC on April 29, 2021. On June 14, 2021, we entered into Securities Purchase Agreements (the " June Purchase Agreement ") with certain accredited investors (the " June Purchasers ") to issue (a) an aggregate of 1, 653, 281 shares of the Company' s Common Stock and / or prefunded warrants to purchase shares of Common Stock at an exercise price of $ 0. 01 per share (the " June Pre- Funded Warrants ") and (b) Series G warrants to purchase up to an aggregate of 1, 653, 281 shares of Common stock, with an exercise price of $ 8. 51 per share (subject to adjustment), for a period of five years from the date of issuance (the " June Warrants ") at a combined purchase price of $ 7. 547 per share of Common Stock and June Warrants (the " June Offering "). In connection with the June Purchase Agreement, we entered into a Registration Rights Agreement with the June Purchasers (the " June Registration Rights Agreement ") on June 14, 2021. Under the terms of the June Registration Rights Agreement, we filed a registration statement on Form S- 1 to register the resale of the shares underlying the securities sold in the June Offering, which registration statement was declared effective by the SEC on July 6, 2021. On November 17, 2022, we entered into a Securities Purchase Agreement~~

~~(the " November Purchase Agreement ") with certain accredited investors (the " November~~ Investors "), pursuant to which we agreed to sell to the ~~November~~ **Series C** Investors (i) **in a registered direct offering,** an aggregate of ~~15~~ **1** , ~~000~~ **793** shares of the Company' s newly- designated Series ~~B~~ **C** convertible preferred stock **, par value $ 0. 0001,** with a stated value of $ 1, 000 per share (the " Series ~~B~~ **C** Preferred Stock "), initially convertible into up to ~~1~~ **448** , **250** ~~935, 485~~ shares of Common Stock (the " **Registered Conversion Shares ") and (ii) in a concurrent private placement, an aggregate of 3, 207 shares of the Series C** Preferred **Stock, initially convertible into up to 801, 750 shares of Common Stock (the " Unregistered Conversion Shares " and, together with the Registered Conversion Shares, the " Series C Conversion** Shares ") at an initial conversion price of $ ~~7~~ **4** . ~~75~~ **00** per share **, as well as warrants** (the " ~~Conversion Price~~ **Series C Warrants** ") ~~, and (ii) warrants (including those issued to the Placement Agent)~~ to acquire up to an aggregate of 1, ~~993~~ **250** , ~~549~~ **000** shares of Common Stock (the " ~~November~~ **Series B** ~~Warrants~~ **Warrant Shares** ") (**the registered direct offering and the concurrent private placement** collectively, the " **Series C Offering** ~~November 2022 Private Placement~~ "). ~~The Conversion Price of the Series B Preferred Stock is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price- based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then applicable Conversion Price (subject to certain exceptions). We are required to redeem the Preferred Shares in 15 equal monthly installments, which commenced on June 1, 2023. The amortization payments due upon such redemption are payable, at our election, in cash, or subject to certain limitations, in shares of Common Stock valued at the lower of (i) the conversion price then in effect and (ii) the greater of (A) a 15 % discount to the average of the three lowest closing prices of the Company' s common stock during the thirty trading day period immediately prior to the date the amortization payment is due or (B) the lower of $ 1. 25 and 20 % of the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) on the date of receipt of Nasdaq Stockholder Approval (as defined below); provided that if the amount set forth in clause B is the lowest effective price, we will be required to pay the amortization payment in cash.~~ In ~~certain situations, we may require holders to convert their Series B Preferred Stock into Preferred Shares. Further, the holders of the Series B Preferred Stock are entitled to dividends of 7 % per annum, compounded monthly, which is payable in cash or shares of Common Stock at our option. To the extent the number of shares of Common Stock issued in~~ connection with the ~~November~~ **Series C Purchase Agreement, on September 10,** ~~2022~~ **2024** ~~Private Placement is greater than anticipated~~ , **we and** the ~~market price~~ **Series C Investors entered into a Registration Rights Agreement (the " Series C Registration Rights Agreement "), pursuant to which we were required to file a resale registration statement with the SEC to register for resale 200 %** of ~~our Common Stock could decline further~~ **the Unregistered Conversion Shares and 200 % of the Series C Warrant Shares. We filed a registration statement for the resale of such securities on October 10, 2024, which was declared effective by the SEC on October 21, 2024** . We are unable to predict whether large amounts of our Common Stock will be sold in the open market. We are also unable to predict whether a sufficient number of buyers of our Common Stock to meet the demand to sell shares of our Common Stock at attractive prices would exist at that time. It is possible that our stockholders will sell the shares of our Common Stock for various reasons. For ~~example~~ **55example** , such stockholders may not believe that our business profile or our level of market capitalization as an independent company ~~fits~~ **fit** their investment objectives. The sale of significant amounts of our Common Stock or the perception in the market that this will occur may lower the market price of our Common Stock. ~~61If~~ **If** securities or industry analysts do not publish research or publish misleading or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our Common Stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage for our Common Stock. If there is no research coverage of our Common Stock, the trading price for shares of our Common Stock may be negatively impacted. If we obtain research coverage for our Common Stock and if one or more of the analysts downgrades our stock or publishes misleading or unfavorable research about our business, our stock price would likely decline. If one or more analyst ceases coverage of our Common Stock or fails to publish reports on us regularly, demand for our Common Stock could decrease, which could cause our Common Stock price or trading volume to decline. We do not expect to pay any cash dividends for the foreseeable future. We do not expect to declare or pay any cash dividend for the foreseeable future. We expect to use future earnings, if any, to fund business growth. Therefore, stockholders will not likely receive any funds absent a sale of their shares. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will only occur if our stock price appreciates. We cannot assure stockholders of a positive return on their investment when they sell their shares, nor can we assure that stockholders will not lose the entire amount of their investment. Provisions in our certificate of incorporation, our bylaws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our Common Stock. Provisions of our articles of incorporation, bylaws, shareholder rights plan or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to change the composition of our Board or to replace or remove our management. These provisions include: ● limitations on the removal of directors; ● advance notice requirements for stockholder proposals and nominations; ● limitations on the ability of stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting; ● limitations on the liability of, and the provision of indemnification to, our director and officers; and ● the ability of our Board to authorize the issuance of blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our Common Stock. In addition, we are subject to Section 203 of the DGCL, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date such person becomes an interested stockholder, unless the business combination or the transaction in which such person becomes an interested stockholder is approved in a prescribed manner. Generally, a " business combination " includes a merger, asset or stock sale, or other transaction resulting in a financial benefit

to the interested stockholder. Generally, an " interested stockholder " is a person that, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15. 0 % or more of a corporation' s voting stock. The existence of this provision may have an anti- takeover effect with respect to transactions not approved in advance by our Board and the anti- takeover effect includes discouraging attempts that might result in a premium over the market price for the shares of our Common Stock. ~~62In~~ **56In** addition, our amended and restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any stockholder (including a beneficial owner) to bring: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee, to us or to our stockholders, (iii) any action or proceeding asserting a claim against us or any current or former director, officer or other employee arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our bylaws (in each case, as they may be amended from time to time), (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our bylaws (including any right, obligation, or remedy thereunder); (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; or (vi) any action asserting a claim governed by the internal affairs doctrine against us or any of our directors, officers or other employees, in all cases to the fullest extent permitted by law and subject to the court' s having personal jurisdiction over the indispensable parties named as defendants. Notwithstanding the foregoing, this exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal district courts of the United States of America shall be the sole and exclusive forum. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. The existence of the foregoing provisions and anti- takeover measures could limit the price that investors might be willing to pay in the future for shares of our Common Stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that investors could receive a premium for their shares of our Common Stock in an acquisition. You may experience dilution of your ownership interests because of the future issuance of additional shares of our Common Stock. Any future issuance of our equity or equity-backed securities will dilute then- current stockholders' ownership percentages and could also result in a decrease in the fair market value of our equity securities, because our assets would be owned by a larger pool of outstanding equity. As described above, we will need additional financing to continue our operations and may raise additional capital through public or private offerings of our common or preferred stock or other securities that are convertible into or exercisable for our common or preferred stock. We may also issue such securities in connection with hiring or retaining employees and consultants (including stock options and other equity compensation issued under our equity incentive plans), as payment to providers of goods and services, in connection with future acquisitions or for other business purposes. Our Board may at any time authorize the issuance of additional common or preferred stock without common stockholder approval, subject only to the total number of authorized common and preferred shares set forth in our Articles of Incorporation. The terms of equity securities issued by us in future transactions may be more favorable to new investors, and may include dividend and / or liquidation preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect. Also, the future issuance of any such additional shares of our common or preferred stock or other securities may create downward pressure on the trading price of our Common Stock. There can be no assurance that any such future issuances will not be at a price (or exercise prices) below the price at which shares of our Common Stock are then traded. We may obtain additional capital through the issuance of preferred stock, which may limit your rights as a holder of our Common Stock. Without any stockholder vote or action, our Board may designate and approve for issuance shares of our preferred stock. The terms of any preferred stock may include priority claims to assets and dividends and special voting rights which could limit the rights of the holders of our Common Stock. The designation and issuance of preferred stock favorable to current management or stockholders could make any possible takeover of us or the removal of our management more difficult. ~~63~~ **57**