

Risk Factors Comparison 2024-03-25 to 2023-03-31 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text** Section

Investing in our securities involves a high degree of risk. You should **consider** carefully ~~consider~~ **the following information** about the risks described below, ~~as well as~~ **together with the** other information ~~included~~ **contained** in this Annual Report on Form 10-K, ~~including our financial statements and~~ **in our** the ~~other~~ related notes ~~public filings~~, **in evaluating our business.** ~~If~~ and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” any of which may be relevant to decisions regarding an investment in or ownership of our securities. The occurrence of any of these ~~the following~~ risks ~~actually occurs~~ could have a significant adverse effect on our reputation, ~~our~~ business, financial condition, results of operations, ~~and future~~ growth ~~prospects would likely be materially~~ and ~~adversely affected~~ ability to accomplish our strategic objectives. We have ~~In these circumstances, the market price of our Common Stock would likely decline.~~ **The Company has** organized the description of these risks into groupings in an effort to enhance readability, but many of the risks interrelate or could be grouped or ordered in other ways, so no special significance should be attributed to the groupings or order below. ~~15Risk~~ ~~19Risk~~ Factor Summary Risks Related to our Business and Product Candidates: · We will need to raise additional financing to support our business objectives. We cannot be sure we will be able to obtain additional financing on terms favorable to us when needed, or at all. If we are unable to obtain additional financing to meet our needs, our operations may be adversely affected or terminated. · We are currently receiving Research and Development, or R & D, tax credits from the ~~United Kingdom (“UK”)~~ in connection with our clinical trials being conducted in the UK. With effect ~~from~~ **for accounting periods starting on or after** April 1, 2024 ~~if~~, expenditure ~~is incurred on certain staffing costs~~ in connection with activities which take place outside the UK as part of our clinical trials, ~~such~~ **will not qualify for R & D tax** credits ~~unless restrictive conditions are met~~ **not expected to be available.** · If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are vital to our business. · Changes in regulatory requirements or other unforeseen circumstances may impact the timing of the initiation or completion of our clinical trials. · We face many of the risks and difficulties frequently encountered by relatively new companies with respect to our operations. ~~We have~~ **The Company has** no mature product candidates and may not be successful in licensing any. · Even if ~~we are~~ **the Company is** successful in licensing lead product candidates, resource limitations may limit our ability to successfully develop them. Risks Related to our Intellectual Property: · If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to our product candidates, and our ability to successfully commercialize any product candidates we may develop, and our science may be adversely affected. · Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. · We may be subject to claims challenging the inventorship of our patents and other intellectual property. · Intellectual property rights do not necessarily address all potential threats. · Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. ~~16Risks~~ ~~20Risks~~ Related to our Securities: · Our Common Stock may be delisted from The Nasdaq Capital Market if ~~we~~ **the Company** cannot maintain compliance with Nasdaq’s continued listing requirements. · If we sell securities in future financings stockholders may experience immediate dilution and, as a result, our stock price may decline. · The price of our securities may be volatile, and you could lose all or part of your investment. Further, we do not know whether an active, liquid and orderly trading market will continue for our securities or what the market price of our securities will be and as a result it may be difficult for you to sell your shares of our securities. · Shares of our Common Stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144 (~~Hi~~) which apply to a former “shell company.” · Sales of our currently issued and outstanding stock may become freely tradable pursuant to Rule 144 and sales of such shares may have a depressive effect on the share price of ~~our~~ **its** Common Stock. **RISKS RELATED TO OUR BUSINESS AND PRODUCT CANDIDATES** **The Company will need to raise additional financing to support our business objectives. The Company cannot be sure the Company will be able to obtain additional financing on terms favorable to us when needed, or at all. If the Company is unable to obtain additional financing to meet our needs, our operations may be adversely affected or terminated.** Since our inception, ~~we have~~ **the Company has** used substantial amounts of cash to fund our research and operations and expect our expenses to increase substantially in the foreseeable future as developing our product candidates and conducting ~~and completing~~ clinical trials will require substantial amounts of capital. ~~We~~ **The Company** will also require a significant additional amount of capital to commercialize any products that are approved in the future. ~~We~~ **The Company** will need to raise additional funds in the near future in order to satisfy our working capital and capital expenditure requirements. ~~We~~ **The Company** may raise additional funds through public or private equity offerings, debt financings, strategic partnerships or alliances, receivables or royalty financings or corporate collaboration and licensing arrangements. ~~We~~ **The Company** cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that ~~we~~ **the Company raise** ~~raises~~ additional capital by issuing equity securities or convertible debt, your ownership may be diluted and the terms of such financings may include liquidation or other preferences that adversely affect the rights of existing stockholders. Any future debt financing into which ~~we~~ **the Company enter** ~~enters~~ may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. These restrictions could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. Debt financings may also be coupled with

an equity component, such as warrants to purchase shares, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If ~~we the Company~~ were to default on such indebtedness, ~~we the Company~~ could lose such assets and intellectual property. If ~~we the Company~~ raise-raises additional funds through strategic partnerships and alliances and licensing arrangements with third parties, ~~we the Company~~ may have to relinquish valuable rights to our product candidates. In addition, if ~~we the Company~~ raise-raises additional funds through corporate collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to products or product candidates or grant licenses on terms that are not favorable to us. Our future capital requirements may depend on a wide range of factors, including, but not limited to: · the costs related to initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates; · any change in the clinical development plans for these product candidates; · the number and characteristics of product candidates that ~~we the Company~~ develop-develops or acquire-acquires; 17-21 · our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements and the terms and timing of such arrangements; · the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments; · the events related to the outcome, timing and cost of meeting regulatory requirements established by the US Drug Enforcement Agency (the "DEA"), the FDA or other comparable foreign regulatory authorities; · the potential costs of filing, prosecuting, defending and enforcing our patent claims and other intellectual property; · changes in economic conditions, including recessionary effects and inflationary pressures; · the costs associated with attracting and retaining skilled personnel; · the costs associated with being a public company; · the cost of defending intellectual property disputes; and · the cost of marketing and generating revenues for any of our product candidates. If ~~we are the Company is~~ unable to raise additional capital when required or on acceptable terms, ~~we the Company~~ may be required to significantly delay, scale back or discontinue one or more of our product development programs or commercialization efforts, or other aspects of our business plan. ~~We The Company~~ also may be required to relinquish, license or otherwise dispose of rights to products or product candidates that ~~we the Company~~ would otherwise seek to commercialize or develop ourselves on terms that are less favorable than might otherwise be available. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited. As described in Part I-II, Item 7 -of this Annual Report on Form 10- K, " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " ~~we the Company~~ entered into the **Equity Line Lincoln Park Agreements** with **an institutional investor Lincoln Park Capital Fund LLC (" Lincoln Park ")** which ~~provide~~ provides , among other things, for the sale by us to **Lincoln Park the institutional investor** of up to \$ 20. 0 million in shares of our Common Stock, subject to the terms of the **Equity Line Lincoln Park Agreements**. Though ~~we have the Company has~~ the right, but not the obligation, to sell to **Lincoln Park the institutional investor** shares of our Common Stock under the **Equity Line Lincoln Park Agreements**, market conditions may not be favorable for us to sell shares of our Common Stock to **Lincoln Park the institutional investor**. Under the terms of the **Equity Line Lincoln Park Agreements**, ~~we are the Company is~~ prohibited from effecting or entering into an agreement to effect any issuance by us or our subsidiaries of shares of our Common Stock involving the issuance of any floating conversion rate or variable priced equity- like securities, not including the prohibition of the issuance and sale of shares of our Common Stock pursuant to an " at- the- market offering " by us exclusively through a registered broker- dealer acting as our agent pursuant to a written agreement between us and such registered broker- dealer. 18 ~~We are The Company is~~ currently receiving Research and Development (" R & D ") tax credits from the UK in connection with our clinical trials being conducted in the UK. With effect from ~~for accounting periods starting on or after~~ April 1, 2024 if , expenditure is incurred on certain staffing costs in connection with activities which take place outside the UK as part of our clinical trials, ~~such will not qualify for R & D tax credits unless restrictive conditions are met~~ not expected to be available. The UK government grants R & D tax credits to companies conducting clinical trials in the UK, as ~~we are the Company is~~ currently doing. This effectively reduces the costs, and the cash ~~we the Company use uses~~ , for our current trials. With effect from ~~for accounting periods starting on or after~~ 1 April 2024 if expenditure is incurred in connection with activities which take place ~~externally provided workers and contractors~~ outside the UK as part of our ~~will no longer be eligible for relief, unless specific conditions are met. Relief for payments to clinical trial participants and certain other expenditure will continue to be available regardless of the location of trials , such credits are not expected to be available. However~~ In addition, if the rate of relief changes or the regime is altered in scope, our production costs could increase significantly. Based ~~based~~ on announcements made as part of the UK Budget ~~but not yet enacted, for accounting periods beginning on March 15, or after 1 April 2023-2024 and which have yet to be enacted,~~ the rate of relief from April 2023 will ~~available to the company may also reduce, depend depending~~ on whether ~~qualifying~~ the company incurs 40 % of its total expenditure on R & D expenditure incurred by . If it does, the value ~~company is treated as at least 30 % of total expenditure so that the company qualifies for a higher rate of relief as will only reduce marginally from April 2023. Otherwise, the rate of repayable credit will reduce materially and-~~ **an R & D intensive company** this will significantly adversely affect the cost of product development. We 22 ~~If the Company fails to comply with our obligations under our patent licenses with third parties, the Company could lose license rights that are vital to our business. The Company is~~ a party to license agreements with NEOMED Institute and the Research Foundation at Stony Brook University, pursuant to which ~~we the Company~~ in- license-licenses key patents and patent applications for our product candidates. These existing licenses impose various diligence, milestone payment, royalty and other obligations on us. If ~~we the Company fail fails~~ to comply with these obligations, our licensors may have the right to terminate the licenses, in which event ~~we the Company~~ would not be able to develop or market the products covered by such licensed intellectual property. In particular, on April 24, 2019, ~~we the Company~~ exercised our option (the " Option Exercise ") pursuant to the Material and Data

Transfer, Option and License Agreement with NEOMED dated as of December 20, 2017, as amended on January 4, 2019 (the “NEOMED Agreement”). In the future, if ~~we are~~ **the Company is** found not to be in compliance with the NEOMED Agreement, our license agreement with the Research Foundation at Stony Brook University (the “Stony Brook Agreement”), or any other license agreements it could materially adversely affect our business, results of operations, financial condition and prospects. If ~~we~~ **the Company fail fails** to comply with any of our license obligations, our licensors may have the right to terminate these agreements, in which event ~~we~~ **the Company** might not be able to develop and market any product candidate that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. ~~We~~ **The Company** may enter into additional licensing agreements in the future and if ~~we~~ **the Company fail fails** to comply with obligations under those agreements, ~~we~~ **the Company** could suffer similar consequences. Changes in regulatory requirements and guidance may occur, and ~~we~~ **the Company** may need to amend clinical trial protocols or our development plan to reflect these changes. Amendments may require resubmitting clinical trial protocols to the FDA or other similar authorities in other jurisdictions and institutional review boards (“IRBs”) for re-examination, which may impact the costs, timing or successful completion of our clinical trials. If ~~we~~ **the Company** experience ~~experiences~~ **delays** in completion of, or if ~~we~~ **the Company** terminate ~~terminates~~ **any** planned clinical trials, the commercial prospects for product candidates may be harmed, and the ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of product candidates. ~~The full~~ **Further, changes in regulatory requirements and policies can** impact ~~of our clinical trials, including due to public health concerns, such as~~ the COVID-19 pandemic ~~on our clinical trial plans, product development, and how a regulatory body reviews study data is difficult to predict, but the pandemic may have a material adverse impact on our business operations, clinical trial plans, and product development, including delays in clinical trial and study participant recruitment, delays in regulatory approval of our product candidates, and the need to expend additional costs and resources.~~ **For example** The pandemic’s impact on the US and global economy and drug product manufacturing and supply chain may also adversely affect our clinical trial plans and drug development. Additionally, depending on the duration of impacts of the COVID-19 pandemic, including stresses on healthcare systems and our clinical trial sites, ~~may have a material impact on~~ our ability to recruit participants for our clinical trials ~~may be significantly impacted, and~~ ~~we~~ **the Company** may not be able to commence or complete our clinical trials as currently planned. ~~We~~ **The Company** may also be required to significantly modify our study protocol, policies and procedures in order to address or accommodate patients and study site needs. Such changes can include modification to protocol inclusion and exclusion criteria, extending the time for patient follow up visits, using telemedicine, phone interviews and other technology to monitor patient safety, all of which will need to be approved by applicable IRBs, ethics committees, and regulatory authorities. **In addition, if the Supreme Court reverses or curtails the Chevron doctrine, which gives deference to regulatory agencies in litigation against FDA and other agencies, more companies may bring lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA’s authority, lead to uncertainties in the industry, and disrupt FDA’s normal operations, which could delay FDA’s review of our marketing applications.** ~~19Geopolitical~~ **Geopolitical** tensions, including the war in Ukraine, ~~and the Israel- Hamas war or other regional conflicts~~ may disrupt investment in our business, supply chains carrying required materials and the movement of people globally. Such disruptions may adversely affect our clinical trials, ~~scope of potential partners~~ and our business generally. **In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U. S. government has made and continues to make significant additional changes in U. S. trade policy and may continue to take future actions that could negatively impact U. S. trade. For example, legislation has been introduced in Congress to limit certain U. S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers’ ability to engage in business in the U. S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and / or results of operations would be materially and adversely affected.** ²³**The Company faces many of the risks and difficulties frequently encountered by relatively new companies with respect to our operations.** Our business objective is to pursue the licensing, development and commercialization of therapeutic treatments that modulate lipid- signaling pathways, including the endocannabinoid system. ~~We have~~ **The Company has** limited operating history as a medical research company engaged in biopharmaceutical research upon which an evaluation of our company and our prospects could be based. There can be no assurance that our management will be successful in being able to commercially exploit the results, if any, from our product development research projects or that ~~we~~ **the Company** will be able to develop products and treatments that will enable us to generate sufficient revenues to meet our expenses or to achieve and / or maintain profitability. If ~~we are~~ **the Company is** unable to raise sufficient capital as needed, ~~we~~ **the Company** may be required to reduce the scope of our planned research and development activities, which could harm our business plans, financial condition and operating results, or cease our operations entirely, in which case, you may lose all your investment. Even if one or more of our product candidates is approved for commercial sale, ~~we~~ **the Company** anticipate ~~anticipates~~ incurring significant costs associated with commercializing any approved product candidate and ~~we~~ **the Company** may not generate significant revenue from sales of such products, resulting in limited or no profitability in the future. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders’ equity and working capital for the foreseeable future. Any failure to become and remain profitable

may adversely affect the market price of our securities, our ability to raise capital and our future viability. One of the key elements of our business strategy is to license technologies or compounds from companies and / or research institutions. ~~We~~ **The Company** may not be able to identify technologies or compounds that are commercially viable, or that are available for licensure under acceptable terms. If ~~we are~~ **the Company is** able to identify suitable technologies or compounds, ~~we~~ **the Company** may be unable to successfully negotiate a license, or maintain the licensing and collaboration arrangements necessary to develop and commercialize any product candidates. ~~We~~ **The Company** may be unable to compete for licenses to available technologies and compounds with companies that are more established than us and have greater financial resources than us. Even if ~~we are~~ **the Company is** successful in licensing programs, ~~we~~ **the Company** may not be able to satisfy development requirements should ~~we~~ **the Company** be unable to raise additional funding. Any failure to establish or maintain licensing or collaboration arrangements on favorable terms could adversely affect our ability to develop and commercialize product candidates, which can adversely affect our business prospects and financial condition. ~~20~~ **Pharmaceutical-- Pharmaceutical** development requires substantial capital, skilled personnel and infrastructure to successfully develop products for the market. The success of our business is highly dependent on our ability to successfully develop, obtain regulatory approval for and commercialize products. ~~We do~~ **The Company does** not currently have the financial resources to fund the full development of any lead product candidate to commercialization and there is no assurance that ~~we~~ **the Company** can raise enough capital to fund full product development. If ~~we are~~ **the Company is** unable to raise additional capital, ~~we~~ **the Company** will not be able to pursue the development of any products and may have to relinquish rights to any products ~~we~~ **the Company** may have licensed. ~~We do~~ **24The Company does** not have any therapeutic products that are approved for commercial sale. Our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of factors. ~~We~~ **The Company** currently ~~do~~ **does** not have any therapeutic products that are approved for commercial sale. ~~We have~~ **The Company has** not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates, if approved in the future. To obtain revenues from sales of our product candidates that are significant or large enough to achieve profitability, ~~we~~ **the Company** must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing therapies with commercial potential. Our ability to generate revenue and achieve profitability depends significantly on our success in many areas, including: · our research and development efforts, including preclinical studies and clinical trials of our product candidates; · developing sustainable, scalable, reliable and cost- effective manufacturing and distribution processes for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own cGMPs, manufacturing facilities and processes; · addressing any competing technological and industry developments; · identifying, assessing, acquiring and / or developing new technology platforms and product candidates across numerous therapeutic areas; · obtaining regulatory approvals and marketing authorizations for product candidates; · launching and commercializing any approved products, either directly or with a collaborator or distributor; · obtaining market acceptance of and acceptable reimbursement for any approved products; · completing collaborations, licenses and other strategic transactions on favorable terms, if at all; · maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know- how; and · attracting, hiring and retaining qualified personnel. ~~21~~ **We have** **The Company has** very limited operating history and capabilities. Although our company was formed in 2011, our current business focus and operations in pharmaceutical development began in 2017. ~~We do~~ **The Company does** not currently have the ability to perform all the functions necessary to develop and commercialize any product candidates. The successful development of any product candidates will require us to perform a variety of functions including, but not limited to: · ~~Identifying~~ **identifying**, licensing and obtaining development programs and lead candidates; · ~~Conducting~~ **conducting** initial research required to identify a lead candidate as the result of intellectual property ~~we have~~ **the Company has** licensed; · ~~Initiating~~ **initiating** preclinical, clinical or other required studies for future product candidates; · ~~Adding~~ **adding** manufacturers and suppliers required to advance our programs; · ~~Obtaining~~ **obtaining** regulatory and marketing approvals for our product candidates that successfully complete clinical studies; · ~~Making~~ **making** milestone or other payments under any license agreements; · ~~Expanding~~ **expanding**, maintaining and protecting our intellectual property portfolio; · ~~Attracting~~ **attracting** and retaining skilled personnel; and · ~~Creating~~ **creating** and maintaining an infrastructure required to support our operations as a public company. ~~Our~~ **25Our** operations continue to be focused on acquiring, developing and securing our proprietary technology and undertaking preclinical and clinical trials of our products. ~~We~~ **The Company** expect ~~expects~~ our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. ~~We~~ **The Company** will need to transition from a company with a research and development focus to a company capable of undertaking commercial activities. ~~We~~ **The Company** may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition. ~~The Company~~ **Our operations and financial results could be adversely impacted by the COVID- 19 pandemic. In December 2019, a novel strain of coronavirus, subsequently named SARS- CoV- 2 (and which causes a disease called “ COVID- 19 ”), was reported to have surfaced in Wuhan, China, which then spread rapidly throughout the globe resulting in significant disruptions to manufacturing, supply chain, markets, and travel world- wide, especially businesses involving activities or operations in China. On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (the “ WHO ”) declared the COVID- 19 outbreak a public health emergency of international concern and on March 12, 2020 the WHO announced the outbreak was a global pandemic. While the extent of the impact of the current COVID- 19 pandemic and its aftermath on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID- 19 outbreak and subsequent variants could have a negative impact on our business, financial condition and operating results. Due to the global pandemic, our recruiting of clinical trial participants could also be slowed or delayed, or in a more severe scenario, our business, financial condition and operating results could be more severely affected. Given the dynamic nature of these circumstances, including the emergence of new variants of the virus and resulting restrictions**

imposed by various governments, the duration of any business disruption or potential impact to our business resulting from the COVID-19 pandemic is difficult to predict and it may increase our costs or expenses. ~~22~~We may experience delays in providing sufficient product for future testing of our candidates due to the ongoing **prior and any future** supply chain limitations caused by COVID-19. Due to **current prior and any future** supply chain disruptions caused by COVID-19, our contract manufacturing organizations may experience an inability to manufacture and produce sufficient quantities of our drug candidates as ~~we the Company~~ **progress progresses** through our regulatory testing and / or approval. Should this happen, ~~we the Company~~ **Company** may not be able to provide sufficient quantities of our drug candidates to complete our testing as currently planned which could delay our ability to bring an approved drug to market. Such a delay may cause us to use more capital than currently planned which may have a material adverse effect on our projected timing of product approval and financials. **After submitting** ~~We may not be able to file~~ Investigational New Drug applications **to commence clinical trials on the timelines we expect, and even if we are able to**, the FDA may not permit us to proceed in a timely manner, or at all. Prior to commencing clinical trials in territories with a regulatory authority ~~we the Company~~ **we the Company** must obtain the necessary approvals to commence the clinical studies. For example, before initiating a clinical trial in the United States for any of our product candidates, ~~we the Company~~ **we the Company** may be required to have an IND in effect for each product candidate. Submission of an IND may not result in the FDA allowing clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials. Once an IND is submitted, the sponsor must wait 30 calendar days before initiating the clinical trial, during which FDA will review the IND and either provide comments or allow the trial to proceed. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or a clinical trial application (the equivalent of an IND in foreign jurisdictions), these regulatory authorities may change their requirements in the future. **The Although we have commenced clinical trials, the** fact that ~~we are the Company is~~ **we are the Company is** pursuing novel technologies may also exacerbate these risks with respect to our product candidates, and as a result ~~we the Company~~ **we the Company** may not meet our anticipated clinical development timelines. Use of our product candidates could be associated with adverse side effects. As with most biopharmaceutical products, use of our product candidates could be associated with side effects or adverse events which can vary in severity and frequency. Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or adverse events may negatively affect our ability to obtain regulatory approval or market our product candidates. Side effects such as toxicity or other safety issues associated with the use of our product candidates could require us to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business if ~~we are the Company is~~ **we are the Company is** found liable. The emergence of unforeseen safety issues or adverse events may lead to regulatory agencies requiring us to conduct additional preclinical or clinical trials regarding the safety and efficacy of our product candidates, which ~~we have the Company has~~ **we have the Company has** not planned or anticipated. ~~We The Company~~ **We The Company** cannot assure you that ~~we the Company~~ **we the Company** will resolve any issues related to any product- related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition. ~~We The Company~~ **We The Company** may also inadvertently fail to report adverse events ~~we the Company~~ **we the Company** become **becomes** aware of within the prescribed timeframe. ~~We The Company~~ **We The Company** may also fail to appreciate that ~~we have the Company has~~ **we have the Company has** become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If ~~we the Company~~ **we the Company** ~~fail fails~~ to comply with our reporting obligations, the FDA or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products. **Clinical 26Clinical** drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and clinical trials may not be predictive of future clinical trial results, and our clinical trials may fail to adequately demonstrate substantial evidence of safety and efficacy of our product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and ~~we the Company~~ **we the Company** cannot be certain that ~~we the Company~~ **we the Company** will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to support obtaining regulatory approval for our product candidates. ~~23~~~~We do~~ **The Company does** not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated by us, regulatory authorities, clinical trial investigators, and ethics committees for a variety of reasons, including failure to: · generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials; · obtain regulatory approval, or feedback on clinical trial design, to commence a clinical trial; · identify, recruit and train suitable clinical investigators; · reach agreement on acceptable terms with prospective CROs and clinical trial sites; · obtain and maintain IRB, approval at each clinical trial site; · identify, recruit, and enroll suitable patients to participate in a clinical trial; · have a sufficient number of patients complete a clinical trial or return for post- treatment follow-up; · ensure clinical investigators observe clinical trial protocol or continue to participate in a clinical trial; · address any patient safety concerns that arise during the course of a clinical trial; · address any conflicts with new or existing laws or regulations; · add a sufficient number of clinical trial sites; · timely manufacture sufficient quantities of a product candidate for use in clinical trials; or · raise sufficient capital to fund a clinical trial. Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' or

caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications ~~we are~~ **the Company is** investigating. ~~24~~**We** **The Company** could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such clinical trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such clinical trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including GCPs or the approved clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in a finding of non-compliance, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. ~~If we~~ **27****If the Company experience experiences** delays in the completion of, or termination of, any clinical trial of our product candidates for any reason, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and the future marketing approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. **Interim, topline and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials. These interim updates are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrolment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock. In addition, the information we choose to publicly disclose regarding a particular study or trial is typically selected from a more extensive amount of available information. Investors may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.** Due to our limited resources, ~~we~~ **the Company** may be forced to focus on a limited number of development candidates which may force us to pass on opportunities that could have a greater chance of clinical success. Due to our limited resources and capabilities, ~~we~~ **the Company** will have to decide to focus on developing a limited number of product candidates. As a result, ~~we~~ **the Company** may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. ~~If we do~~ **the Company does** not accurately evaluate the commercial potential or target market for a particular product candidate, ~~we~~ **the Company** may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. ~~We~~ **28****The Company** will need to rely on third parties to conduct our preclinical research and clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such research or trials. ~~We~~ **The Company plan plans** to rely on third- party CROs to conduct the majority of our preclinical research studies and our clinical trials. In addition, ~~we~~ **the Company plan plans** to rely on other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. There is no assurance ~~we~~ **the Company** can obtain the services ~~we~~ **the Company need needs** at commercially reasonable prices or within the timeframes ~~we~~ **the Company desire desires**. Even though ~~we~~ **the Company** will enter into agreements governing these third parties' activities, ~~we~~ **the Company** will have limited influence over their actual performance, and ~~we~~ **the Company** will control only certain aspects of their activities. Further, agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the CROs. If there is any dispute or disruption in our relationship with our contractors or if ~~we~~ **the Company need needs** to enter into alternative arrangements, that will delay our product development activities.

25Our-- **Our** reliance on third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, ~~we~~ **the Company** will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. If any of our CROs' processes, methodologies or results are determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely affected. Moreover, the FDA requires us to comply with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, and clinical trial sites, as well as CROs. If ~~we~~ **the Company** or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, our clinical trials may be delayed or ~~we~~ **the Company** may be required to repeat such clinical trials, which would delay the regulatory approval process. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. These third parties may not assign as great a priority to our programs or pursue them as diligently as ~~we~~ **the Company** would if ~~we~~ **the Company** were undertaking such programs ourselves. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or if the quality of the clinical data they obtain is compromised due to the failure to conduct our clinical trials in accordance with regulatory requirements or our stated protocols, ~~we~~ **the Company** will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. ~~We~~ **The Company** currently ~~have~~ **has** no marketing and sales organization and have no experience in marketing products. If ~~we~~ **the Company is** unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved in the future, ~~we~~ **the Company** may not be able to generate product revenue. ~~We~~ **The Company** currently ~~do~~ **does** not have sales, marketing or distribution capabilities and do not have experience as a company in commercializing products. If ~~we~~ **the Company** ~~develop~~ **develops** internal sales, marketing, and distribution organization, this would require significant capital expenditures, management resources and time, and ~~we~~ **the Company** would have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If ~~we~~ **the Company is** unable or decide not to establish internal sales, marketing, and distribution capabilities, ~~we~~ **the Company** ~~expect~~ **expects** to pursue collaborative arrangements regarding the sales, marketing, and distribution of our future products. However, ~~we~~ **the Company** may not be able to establish or maintain such collaborative arrangements, or if ~~we~~ **the Company is** able to do so, their sales forces may not be successful in marketing our future products. Any revenue ~~we~~ **the Company** ~~receive~~ **receives** would depend upon the efforts of such third parties, which may not be successful. ~~We~~ **The Company** may have little or no control over the sales, marketing, and distribution efforts of such third parties and our revenue from product sales may be lower than if ~~we~~ **the Company** had commercialized our product candidates ourselves. ~~We~~ **The Company** also ~~face~~ **faces** competition in our search for third parties to assist us with the sales, marketing, and distribution efforts of our product candidates, if approved. There can be no assurance that ~~we~~ **the Company** will be able to develop internal sales, marketing distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product in the United States or overseas. ~~If~~ **29If** our contract manufacturing organization for materials to be used in our clinical trials fails to supply us with the necessary materials, ~~we~~ **the Company** may be unable to complete our clinical trials on a timely basis, if at all. ~~We~~ **have **The Company** ~~has~~ entered into an agreement with a third party to handle the manufacturing supply chain for our product candidate ART27. 13. If this manufacturer is unable or unwilling to provide us with sufficient quantities of our product candidate to meet its demands or fails to meet its standards of quality or other specification or to achieve drug cGMP compliance, ~~we~~ **the Company** may not be able to locate any alternative suppliers or enter into commercially reasonable agreements with substitute suppliers in a timely manner or at all. 26**We** **Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce an alternative formulation of one or more of our product candidates during the course of our clinical trials. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue. The Company** may depend on third parties for clinical and commercial supplies, including, in some instances, a single supplier. ~~We~~ **The Company** may depend on third- party suppliers for clinical and commercial supplies, including the active ingredients which are used in our product candidate. These supplies may not always be available to us at the standards ~~we~~ **the Company** ~~require~~ **requires** or on terms acceptable to us, or at all, and ~~we~~ **the Company** may not be able to locate alternative suppliers in a timely manner, or at all. If ~~we~~ **the Company is** unable to obtain necessary clinical or commercial supplies, its manufacturing operations and clinical trials and the clinical trials of our collaborators may be delayed or disrupted, and its business and prospects may be materially and adversely affected as a result. ~~We~~ **The Company** may rely on a single supplier for certain of its supplies. If this supplier is unable to supply to us in the quantities ~~we~~ **the Company** ~~require~~ **requires**, or at all, or otherwise defaults on its supply obligations to us, ~~we~~ **the Company** may not be able to obtain alternative**

supplies from other suppliers on acceptable terms, in a timely manner, or at all. ~~If~~ **30** ~~If~~ any of our offices become damaged or inoperable, or ~~we are~~ **the Company is** required to vacate our facilities, our ability to pursue our research and development efforts may be jeopardized. ~~We~~ **The Company** currently ~~do~~ **does** not have any manufacturing facilities. ~~We~~ **The Company** also ~~do~~ **does** not own any properties, laboratories, or manufacturing facilities. However, ~~we have~~ **the Company has** leased office space in Solana Beach, California and a location near Manchester, United Kingdom. Our facilities could be harmed or rendered inoperable by natural or human- made disasters, including earthquakes, fires, power shortages, nuclear, and radiation accidents, telecommunications failures, financial institution collapses, water shortages, famines, pestilence, floods, hurricanes, typhoons, tornadoes, extreme weather conditions, medical epidemics, pandemics, such as the COVID- 19 global pandemic, cyber warfare, national and international conflict, terrorism, climate change, and other natural or human- made disasters or other business interruptions, for which ~~we are~~ **the Company is** predominantly self- insured. Any of these may render it difficult or impossible for us to continue company operations. If any of our facilities is inoperable for even a short period of time, the interruption in research and development may result in harm to our reputation and increased costs, which would have a material adverse effect on our business, financial condition, and results of operations. Furthermore, it could be costly and time- consuming to repair or replace our facilities and the equipment ~~we~~ **the Company use** **uses** to perform our research and development work. Even if ~~we are~~ **the Company is** successful in licensing or developing research programs and / or product candidates, ~~we~~ **the Company** or our licensors must maintain the intellectual property. Our commercial success is significantly dependent on intellectual property related to any product candidates and technologies ~~we~~ **the Company** may either acquire, license, or develop internally. ~~We are~~ **The Company is** currently the licensee of multiple issued patents and pending patent applications and ~~we~~ **the Company** ~~intend~~ **intends** to license additional technologies from pharmaceutical and biotechnology companies, and research institutions. In addition, ~~we have~~ **the Company has** one US patent, one US patent application, and two foreign patent applications directed to a solid- state CBD composition. Our success depends in large part on our and our licensor' s ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and product candidates. In some circumstances, ~~we~~ **the Company** may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that ~~we~~ **the Company** ~~license~~ **licenses** from third parties. Therefore, ~~we~~ **the Company** cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights ~~we have~~ **the Company has** licensed may be reduced or eliminated. ~~27~~ ~~The~~ ~~patent~~ ~~position~~ ~~of~~ ~~biotechnology~~ ~~and~~ ~~pharmaceutical~~ ~~companies~~ ~~generally~~ ~~is~~ ~~highly~~ ~~uncertain~~, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our and our licensor' s patent rights are highly uncertain. Our and our licensor' s pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws, including global waivers and patent removals which are being considered for COVID vaccines, in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, ~~we~~ **the Company** cannot be certain that ~~we~~ **the Company** or our licensor were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that ~~we~~ **the Company** or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is generally entitled to the patent. ~~We~~ **The Company** may become involved in opposition or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our product candidates without infringing third- party patent rights. ~~Even~~ ~~31~~ ~~Even~~ if any owned and / or licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. The costs and other requirements associated with filing new patent applications, and the ongoing cost of prosecuting pending patent applications and maintenance of issued patents are material to us. Bearing these costs and complying with these requirements are essential to procurement and maintenance of patents integral to our product candidates. Legal, filing costs, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or patent applications will come due for payment periodically throughout the lifecycle of patent applications and issued patents. In order to help ensure that ~~we~~ **the Company** ~~complies~~ **complies** with any required fee payment, documentary and / or procedural requirements as they might relate to any patents for which ~~we are~~ **the Company is** an assignee or co- assignee, ~~we~~ **the Company** ~~employ~~ **employs** legal help and related professionals as needed to comply with those requirements. Failure to meet a required fee payment, document production or

procedural requirement can result in the abandonment of a pending patent application or the lapse of an issued patent. In some instances, the defect can be cured through late compliance, but there are situations where the failure to meet the required deadline cannot be cured. Such an occurrence could compromise the intellectual property protection around a preclinical or clinical product candidate and possibly weaken or eliminate our ability to protect our eventual market share for that product candidate. ~~28Our~~ **Our** ability to research, develop and commercialize any product candidates is dependent on our ability to acquire, maintain or utilize third party contract research facilities that possess licenses relating to controlled substances and the dispensing of prescription products. In the United States, the DEA regulates the use of chemicals for medical research and / or commercial development, including the requirement of annual registrations to manufacture or distribute cannabinoid- based pharmaceuticals. ~~We do~~ **The Company does** not currently conduct manufacturing or repackaging / relabeling of any product candidates in the United States, however ~~we~~ **the Company intend-intends** to conduct research on cannabinoids, including naturally- occurring cannabinoids, which are currently considered Schedule I controlled substances. ~~We~~ **The Company plan plans** to obtain the required licenses in the territories regulating the possession and supply of cannabinoids and to utilize third party contractors to conduct research who have the required registrations, however there is no assurance that ~~we~~ **the Company** will be successful in obtaining the required licenses or that ~~we~~ **the Company** will be successful identifying or engaging third party contractors who have the required registrations. ~~We are~~ **The Company is** conducting a significant portion of our research in the United Kingdom, where licenses to cultivate, possess and supply certain cannabinoids for medical research are granted by the Home Office on an annual basis. ~~We~~ **The Company** currently ~~possess~~ **possesses** the required licenses to do our research in the United Kingdom. Our research must be conducted within research institutions that also possess required licenses. If ~~we are~~ **the Company is** unable to conduct research at institutions that possess required licenses, or if those licenses are not obtained or renewed in the future, ~~we~~ **the Company** may not be in a position to engage in or carry out research and development programs in the United Kingdom. In order to carry out research in countries other than the United States and the United Kingdom, similar licenses to those outlined above may be required to be issued by the relevant authority in each country. In addition, ~~we~~ **the Company** will be required to obtain licenses to export from the US or the UK, and to import into the recipient country. ~~We~~ **The Company** may also conduct a portion of our research in Canada, where ~~we are~~ **the Company is** currently collaborating on certain research at the University of Western Ontario, and in Ireland, where ~~we~~ **the Company** currently ~~have~~ **has** multiple research collaborations with Trinity College Dublin. To date, ~~we~~ **the Company has** not obtained controlled substance import, export, or supply licenses in any countries, except the United Kingdom. ~~We do~~ **The Company does** not have an established track record of obtaining such required licenses and there is no assurance ~~we~~ **the Company** will be able to obtain or maintain such licenses in the future, which could restrict our ability to conduct the research required for development and commercialization of our lead products. ~~Any~~ **32Any** product candidates ~~we~~ **the Company develop-develops** may be subject to US controlled substance laws and regulations and similar controls in territories outside the US where ~~we are~~ **the Company is** conducting research. Failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition. Some of our product candidates may contain controlled substances as defined in the federal Controlled Substances Act of 1970 (the “ CSA ”) in the US Controlled substances are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements that are administered and enforced by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently “ accepted medical use ” in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the US Pharmaceutical products approved for use in the United States that comprise or contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances presenting the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs by licensed and DEA- registered health care providers is further restricted. For example, they may not be refilled without a new prescription. ~~29Schedule~~ **Schedule I** controlled substances once approved for medical use in the United States may be placed in Schedules II- V, since marketing approval by the FDA satisfies the “ accepted medical use ” requirement. If and when any of our product candidates receive FDA approval, the DEA will make a scheduling determination within ninety days, taking into account recommendations from the FDA controlled substances staff, in order to place the product in a schedule other than Schedule I so that it may be prescribed to patients in the US Furthermore, if the FDA, DEA, or any foreign regulatory authority subsequently determines that any approved and commercialized cannabinoid- based products may have potential for abuse, it may require us to generate more clinical or other data to establish whether or to what extent the substance has an abuse potential, which could result in a re-scheduling of the product and increase the costs associated with marketing that product. Prior to June 2018, GW Pharmaceuticals was developing a phytocannabinoid CBD product designated as Schedule I. Since the FDA approval in June 2018 of Epidiolex[®] in the US, the DEA has removed it from the list of Schedule I chemicals and from the list of controlled substances. DEA registration and inspection of facilities. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining the necessary registrations may result in delay of the importation, manufacturing, or distribution of any cannabinoid derived products ~~we~~ **the Company** may develop. Furthermore, failure to maintain compliance with the CSA, particularly non- compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition,

and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings. State-controlled substances laws. Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law because the states are separate jurisdictions, they may separately schedule our product candidates as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which ~~we-the Company obtain-obtains~~ federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. ~~We-The Company~~ or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law. ~~Clinical-33Clinical~~ trials. It is possible some compounds ~~we-the Company develop-develops~~ may contain cannabinoids, which may be designated as Schedule I substances, therefore, to conduct clinical trials in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our lead products, as applicable, and to obtain the product from our importer. If the DEA delays or denies the grant of a research registration to one or more research sites, the clinical trial could be significantly delayed, and ~~we-the Company~~ could lose clinical trial sites. The importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import. ~~We-do~~ ~~The Company does~~ not currently conduct any clinical trials, clinical material manufacturing or repackaging / relabeling in the US; however, ~~we-are-the Company is~~ subject to similar laws and regulations in the UK and other countries where ~~we-are-the Company is~~ conducting a clinical trial and have contracted for clinical material manufacturing. Importation. If one of our product candidates is approved and classified as a Schedule II or III substance, an importer can import for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments / estimates to the International Narcotics Control Board which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect product availability and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third party comments to be submitted. It is always possible a competitor could take this opportunity to make adverse comments that delay the grant of an importer registration. ~~30If~~ ~~If~~ one of our product candidates is approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If a product is listed as a Schedule II substance, ~~we-the Company~~ will not be allowed to import that drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. It is always possible the DEA could find that the active substance in a product, even if it is a plant derived substance, could be manufactured in the US. Moreover, Schedule I controlled substances, have never been registered with the DEA for importation commercial purposes, only for scientific and research needs. Therefore, if any of our future products could not be imported, that product would have to be wholly manufactured in the United States, and ~~we-the Company~~ would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity. Manufacturing in the United States. If, because of a Schedule II classification or voluntarily, ~~we-the Company~~ were to conduct manufacturing or repackaging / relabeling in the United States for clinical material, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of any future product candidates, if the active ingredient in the final dosage form is a cannabinoid and is currently a Schedule I controlled substance it would be subject to such quotas as these substances could remain listed on Schedule I. The annual quota allocated to us or our contract manufacturers for the active ingredients in our products may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers' procurement and / or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and operations. Distribution in the United States. If any of our product candidates is scheduled as Schedule II or III, ~~we-the Company~~ would also need to identify wholesale distributors with the appropriate DEA and state registrations and authority to distribute the product to pharmacies and other health care providers. ~~We-The Company~~ would need to identify distributors to distribute the product to pharmacies; these distributors would need to obtain Schedule II or III distribution registrations. The failure to obtain, or delay in obtaining, or the loss any of those registrations could result in increased costs to us. If any of our product candidates is a Schedule II drug, pharmacies would have to maintain enhanced security with alarms and monitoring systems, and they must adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying either or both products. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products. ~~Our-34Our~~ product ~~candidates development projects~~, if approved, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue. Even when and if product development is successful and regulatory approval has been obtained, our ability to generate significant revenue depends on the acceptance of our product candidates by physicians and patients. ~~We-The Company~~ cannot assure that any of our product candidates will achieve the expected market acceptance and revenue, if and when ~~we-the Company obtain-obtains~~ the regulatory approvals. The market acceptance of any of our potential products depends on a number of factors, including the indication statement and warnings approved by regulatory authorities in the drug label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payers such as government health care

systems and insurance companies, the price of the product, the nature of any post- approval risk management plans mandated by regulatory authorities, competition, and marketing and distribution support. Any factors preventing or limiting the market acceptance of our products could have a material adverse effect on our business, results of operations and financial condition.

~~31~~~~Results~~ **Results** of preclinical studies and earlier clinical trials are not necessarily predictive indicators of future results. Any positive results from future preclinical testing of our product candidates and potential clinical trials may not necessarily be predictive of the results from Phase 1, Phase 2, or Phase 3 clinical trials. In addition, our interpretation of results derived from clinical data, or our conclusions based on our preclinical data may prove inaccurate. Frequently, pharmaceutical and biotechnology companies have suffered significant setbacks in clinical trials after achieving positive results in preclinical testing and early clinical trials, and ~~we the Company~~ cannot be certain that ~~we the Company~~ will not face similar setbacks. These setbacks may be caused by the fact that preclinical and clinical data can be susceptible to varying interpretations and analyses. Furthermore, certain product candidates performed satisfactorily in preclinical studies and clinical trials, but nonetheless failed to obtain FDA approval or a marketing authorization granted by the European Commission. If ~~we the Company fail~~ **fails** to produce positive results in our clinical trials for our product candidates, the development timeline and regulatory approval and commercialization prospects for them and as a result our business and financial prospects, would be materially adversely affected. Clinical trials of cannabinoid- based product candidates and lipid- ~~signalling~~ **signaling** modulators are novel with very limited or non- existing history; ~~we the Company face~~ **faces** a significant risk that the trials will not result in commercially viable products and treatments. At present, there is only a very limited documented clinical trial history related to cannabinoids and lipid- ~~signalling~~ **signaling** modulators from which ~~we the Company~~ can derive any scientific conclusions or prove that our present assumptions for the current and planned research are scientifically compelling. While ~~we are~~ **the Company is** encouraged by the limited results of clinical trials by others, there can be no assurance that any clinical trial will result in commercially viable products or treatments. Clinical trials are expensive, time consuming and difficult to design and implement. ~~We~~ **The Company**, as well as the regulatory authorities, may suspend, delay, or terminate our clinical trials at any time, may require us, for various reasons, to conduct additional clinical trials, or may require a particular clinical trial to continue for a longer duration than originally planned, including, among others: · lack of effectiveness of any formulation or delivery system during clinical trials; · discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues; · slower than expected rates of subject recruitment and enrollment rates in clinical trials; · delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints; · delays in obtaining regulatory authorization to commence a trial, including IRB **or Ethics Committee** approvals, licenses required for obtaining and using cannabinoids for research, either before or after a trial is commenced; · unfavorable results from ongoing ~~pre-non~~ clinical studies and clinical trials; · patients or investigators failing to comply with study protocols; · patients failing to return for post- treatment follow- up at the expected rate; · sites participating in an ongoing clinical study withdraw, requiring us to engage new sites; · third- party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or act in ways inconsistent with the established investigator agreement, clinical study protocol, good clinical practices, and other IRB requirements; · ~~third-~~ party entities do not perform data collection and analysis in a timely or accurate manner or at all; or · regulatory inspections of our clinical studies require us to undertake corrective action or suspend or terminate our clinical studies. ~~Any~~ **35Any** of the foregoing could have a material adverse effect on our business, results of operations and financial condition. ~~32~~~~Changes~~ **Changes** in consumer preferences and acceptance of cannabinoid- derived products and any negative trends will adversely affect our business. ~~We are~~ **The Company is** substantially dependent on initial and continued market acceptance and proliferation of cannabinoid- derived therapeutic treatments, and specifically ART12. 11, our CBD cocrystal. ~~We~~ **The Company believe** **believes** that as cannabinoid- derived products become more widely accepted by the medical and scientific communities and the public at large, stigma associated with cannabinoid- derived products and treatments will moderate and, as a result, consumer demand is likely to continue to grow. However, ~~we the Company~~ cannot predict the future growth rate and size of the market, assuming that the regulatory framework is favorable of which there can be no assurance. Any negative outlook on cannabinoid- derived products and treatments could adversely affect our business prospects. In addition, while some may believe that large, well- funded pharmaceutical and other related businesses and industries may have material economic reasons to be in strong opposition to cannabinoid- based products, ~~we do~~ **the Company does** not believe that it is accurate. Despite the fact that several large pharmaceutical companies are already marketing FDA approved cannabinoid- based or ECS targeting therapies, it remains relatively uncommon among the global pharmaceutical giants. The pharmaceutical industry is also well- funded with a strong and experienced lobby presence at both the federal and state levels in the US as well as internationally, that surpasses financial resources of the current group of research and development companies working on product candidates that modulate the endocannabinoid system. Any effort the pharmaceutical lobby could or might undertake to halt or delay the development of cannabinoid- based products could have a detrimental impact on our business. These pressures could also limit or restrict the introduction and marketing of any such cannabinoid- derived product. Adverse publicity regarding misuse or adverse side effects from cannabinoid- derived products may adversely affect the commercial success or marketability. The nature of our business attracts and may be expected to continue to attract a high level of public and media interest and, in the event of any related adverse publicity, ~~we~~ **the Company** may not succeed in monetizing our products and treatments. Our product candidates may contain controlled substances, the use of which may generate public controversy. Since our product candidates may contain controlled substances, their regulatory approval may generate public controversy or scrutiny. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our product candidates. These pressures could also limit or restrict the introduction and marketing of our product candidates. Adverse publicity from misuse or adverse side effects cannabinoid- derived products may adversely affect the commercial success or market penetration achievable by our product candidates. The nature of our business will likely attract a high- level of public and media interest, and in the event of

any resultant adverse publicity, our reputation may be harmed. To date, the FDA has only approved one plant- derived cannabinoid product as safe and effective for initial indications related to epilepsy in children. The FDA is aware that there is considerable interest in the use of cannabinoids to attempt to treat a number of medical conditions. Before conducting testing in humans in the US of a drug that has not been approved by the FDA, ~~we~~ **the Company** will need to submit an IND application to the FDA. Failure to comply with applicable US requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications (“ NDAs ”), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

~~33Laws~~ **36Laws** and regulations affecting therapeutic uses of cannabinoids are constantly evolving. The constant evolution of laws and regulations affecting the research and development of cannabinoid- based pharmaceutical products and treatments could detrimentally affect our business. Laws and regulations related to the therapeutic uses of cannabinoids are subject to changing interpretations. These changes may require us to incur substantial costs associated with legal and compliance fees and ultimately require us to alter our business plan. Furthermore, violations or alleged violations of these laws could disrupt our business and result in a material adverse effect on our operations. In addition, ~~we~~ **the Company** cannot predict the nature of any future laws, regulations, interpretations or applications of laws and regulations and it is possible that new laws and regulations may be enacted in the future that will be directly applicable and harmful to our business. Cannabinoid- based research activities in the pharmaceutical industry may make it difficult to obtain insurance coverage. In the event that ~~we~~ **the Company** ~~decide~~ **decides** to commence research based on plant- derived cannabinoids in the US, obtaining and maintaining necessary insurance coverage, for such things as workers compensation, general liability, product liability and directors’ and officers’ insurance, may be more difficult and expensive for us to find because of our research directions utilizing cannabinoids. There can be no assurance that ~~we~~ **the Company** will be able to find such insurance, if needed, or that the cost of coverage will be affordable or cost- effective. If, either because of unavailability or cost prohibitive reasons, ~~we are~~ **the Company is** compelled to operate without insurance coverage, ~~we~~ **the Company** may be prevented from entering certain business sectors, experience inhibited growth potential and / or expose us to additional risks and financial liabilities. ~~We~~ **The Company** ~~face~~ **faces** a potentially highly competitive market. Demand for medical cannabinoid- derived products is dependent on a number of social, political and economic factors that are beyond our control. While ~~we~~ **the Company** ~~believe~~ **believes** that demand for such products will continue to grow, there is no assurance that such increase in demand will happen, that ~~we~~ **the Company** will benefit from any demand increase or that our business, in fact, will ever become profitable. The emerging markets for cannabinoid- derived products and medical research and development are and will likely remain competitive. The development and commercialization of pharmaceutical products in general is highly competitive. ~~We~~ **The Company** ~~compete~~ **competes** with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as products and processes being developed by universities and other research institutions. Many of our competitors have developed, are developing, or will develop products and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that may enter the market. For some of our product development directions, other treatment options are currently available, under development, and may become commercially available in the future. If any of our product candidates is approved for the diseases and conditions ~~we are~~ **the Company is** currently pursuing, they may compete with a range of therapeutic treatments that are either in development or currently marketed. ~~34Changes~~ **Changes** in legislation or regulation in the health care systems in the United States and foreign jurisdictions may affect us. Our ability to successfully commercialize our products may depend on how the US and other governments and / or health administrations provide coverage and / or reimbursements for our products. The ongoing efforts of governments, insurance companies, and other participants in the health care services industry to reduce health care costs may adversely affect our ability to achieve profitability . **For example, in August 2022, Congress passed the Inflation Reduction Act (IRA), which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high- priced single- source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out- of- pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including pharmaceutical companies, the U. S. Chamber of Commerce, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. Further, uncertainties created by the IRA and additional government constraints on drug pricing could reduce valuation of companies and decrease funding in new drug development, which can have a material impact on our business. In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, restrictions on certain product access and marketing cost disclosure and transparency measures. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Further, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida’s Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize**

our product candidates. In certain foreign markets, including countries in the European Union (“ E. U. ”) and the UK, pricing of prescription pharmaceuticals is subject to governmental control. Price negotiations with governmental authorities may range from 6 to 12 months or longer after the receipt of regulatory marketing approval for a product. Our business could be detrimentally impacted if reimbursements of our products are unavailable or limited if pricing is set at unacceptable levels. ~~We are~~ **37The Company is** highly dependent on our key personnel, and if ~~we are~~ **the Company is** not successful in attracting and retaining highly qualified personnel, ~~we~~ **the Company** may not be able to successfully implement our business strategy. Our ability to compete in our highly competitive industry depends upon our ability to attract and retain highly qualified managerial, scientific, and medical personnel. ~~We are~~ **The Company is** highly dependent on our Chief Executive Officer, Chief Financial Officer, President, Treasurer and Secretary, Gregory D. Gorgas. The loss of the services of Mr. Gorgas, and our inability to find a suitable replacement could result in delays in research and development and product development and **significantly** harm our business. Additionally, although ~~we have~~ **the Company has** entered into an employment agreement with Mr. Gorgas, this employment agreement provides for at- will employment, which means that Mr. Gorgas could leave our employment at any time, with or without notice. ~~We~~ **The Company maintain maintains** a “ key person ” insurance policy on the life of Mr. Gorgas. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable service providers to remain at our company, in addition to salary and cash incentives, ~~we have~~ **the Company has** issued stock options and restricted stock awards that vest over time. The value to service providers of stock options and restricted stock awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our success depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior managers and scientific and medical personnel. If ~~we are~~ **the Company is** not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations. ~~We~~ **The Company** will need to grow the size and capabilities of our organization, and ~~we~~ **the Company** may experience difficulties in managing this growth. To execute our business plan, ~~we~~ **the Company** will need to rapidly add other management, accounting, regulatory, and scientific staff. ~~We~~ **The Company** currently ~~have four~~ **has five** employees and **utilizes** approximately twenty **- five** consultants and contractors. ~~We~~ **The Company** will need to attract, retain and motivate a significant number of new additional managerial, operational, sales, marketing, financial, and other personnel, as well as highly skilled scientific and medical personnel, and to expand our capabilities to successfully pursue our research, development, manufacturing and commercialization efforts and secure collaborations to market and distribute our products. This growth may strain our existing managerial, operational, financial and other resources. ~~We~~ **The Company** also ~~intend~~ **intends** to add personnel in our research and development and regulatory departments as ~~we~~ **the Company** ~~expand~~ **expands** our clinical trial and research capabilities. Moreover, ~~we~~ **the Company** will need to hire additional accounting and other personnel and augment our infrastructure as ~~we~~ **the Company** ~~continue~~ **continues** to grow ~~the company~~. Any inability to attract and retain qualified employees to enable our planned growth and establish additional capabilities or our failure to manage our growth effectively could delay or curtail our product development and commercialization efforts and harm our business. ~~35We are~~ **The Company is** currently reliant on consultants to oversee critical activities and perform services on behalf of the ~~company~~ **Company**. Due to our limited financial resources, ~~we have~~ **the Company has** engaged consultants to work on a part-time basis to oversee critical activities and perform services on behalf of the company. Even if ~~we are~~ **the Company is** successful in raising additional capital and require those activities and services be performed by full- time employees, there is no guarantee that ~~we~~ **the Company** will be able to hire our current consultants or consultants with similar background and experience to oversee those functions or perform services on behalf of the company. ~~We are~~ **The Company is** also at risk that the consultants ~~we~~ **the Company** ~~use~~ **uses** may not be able to perform services on a timely basis for us as opposed to other companies who may offer greater compensation or more opportunity than ~~we do~~ **the Company does**, and that those consultants may eventually decide to accept full- time employment with other companies, some of which could be a direct competitor to us. ~~We have~~ **38The Company has** incurred losses since inception and cannot assure that ~~we~~ **the Company** will ever achieve or sustain profitability. ~~We have~~ **The Company has** incurred losses since inception. ~~We~~ **The Company** ~~expect~~ **expects** to continue to incur significant expenses and increasing operating and net losses for the foreseeable future. To date, ~~we have~~ **the Company has** financed our operations primarily through the sale of equity securities. To date our primary activities have been limited to, and our limited resources have been dedicated to, raising capital, non- clinical research on our programs, recruiting service providers, negotiating with business partners and licensors of intellectual property, filing patent applications, and complying with public reporting requirements. ~~We have~~ **The Company has** never been profitable and do not expect to be profitable in the foreseeable future. ~~We~~ **The Company** ~~expect~~ **expects** our expenses to increase significantly as ~~we~~ **the Company** ~~pursue~~ **pursues** our objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, and ~~we~~ **the Company** ~~expect~~ **expects** to continue to incur significant expenses and operating losses over the next several years. Our prior and continuing losses have had and will continue to have an adverse effect on our stockholders’ equity and working capital. ~~We~~ **The Company** cannot assure that ~~we~~ **the Company** will ever be able to achieve profitability. Even if ~~we~~ **the Company** ~~achieve~~ **achieves** profitability, ~~we~~ **the Company** may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, license additional programs, establish or maintain development efforts, obtain regulatory approvals, or continue operations. **If our information technology systems or data, or those of third parties upon which we depend, are compromised, adverse consequences may follow. These consequences include business operation disruptions, litigation, regulatory investigations or actions, fines and penalties, reputational harm, and financial losses. The operation of our business is dependent on information technology systems and infrastructure. We may process confidential, and sensitive,**

including personal data (such as health- related data), intellectual property, and proprietary business information (collectively, sensitive information) in the ordinary course of our business. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such information. We have also outsourced some of our operations (including parts of our information technology infrastructure) to a number of third- party service providers who may have, or could gain, access to sensitive information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties. Cyberattacks, malicious internet- based activity, and online and offline fraud are increasing in frequency, persistence, sophistication and intensity. These threats come from a variety of sources, including personnel (such as through theft or misuse), computer “ hackers, ” and sophisticated nation states. Some actors now engage and are expected to continue to engage in cyberattacks, including, without limitation, nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. We and the third parties upon which we rely may be subject to a variety of evolving threats, including, but not limited to, personnel misconduct or error, supply- chain attacks, ransomware attacks, malware, malicious code (such as viruses), denial- of- service attacks, social engineering attacks (including “ phishing ”), server malfunctions, telecommunication failures, software or hardware failures, loss of data or other technology assets, adware, earthquakes, fires, floods, and other similar threats. We have been the target of events of this nature and expect them to continue. Ransomware attacks, including by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners’ supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third- party information technology systems that support us and our services. Additionally, many of our employees who work from home at least part of the time, utilizing network connections outside our locations, which may increase risks to our information technology systems and data. Moreover, the prevalent use of mobile devices by our employees and third- party service providers to access confidential information increases the risk to our information technology systems and data. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our proprietary or sensitive information. A security incident or other interruption could disrupt our ability to conduct our business operations and divert significant resources. Though we have insurance that may cover some of the costs and fees resulting from a cyberattack, data security incident, or data breach, that insurance may not be sufficient to cover all of the costs, fees, losses, damages, fines, and penalties that may arise from a data security incident. We may allocate substantial resources and / or adjust our business operations to safeguard against security incidents. Our data privacy and security obligations necessitate the implementation and maintenance of targeted security protocols and tools. These measures adhere to industry standards and are designed to protect our information technology systems, as well as our proprietary and sensitive information. While we have implemented security measures to safeguard our information technology systems and infrastructure, there is no absolute guarantee that these measures will completely thwart cyberthreats, attacks, security incidents, data breaches, malware, ransomware, and other disruptions that could harm our business. The dynamic nature of threats and their sophistication means that vulnerabilities may elude detection until after an incident occurs. Despite our diligent efforts to identify and address vulnerabilities, success is not assured. Additionally, delays in implementing remedial measures to tackle identified vulnerabilities may occur. Furthermore, inadequate internal accounting controls related to security incidents and cybersecurity could impact the accuracy and timeliness of our financial statements, potentially leading to regulatory scrutiny. 39Compliance with data privacy and security obligations, including data breach notification laws in the US and other jurisdictions, may necessitate notifying relevant stakeholders about security incidents. Such disclosures come at a significant cost, and failure to comply with these requirements could have adverse consequences. If we (or a third party on whom we rely) encounter a security incident or are perceived to have experienced one, we may face various negative outcomes. These include government enforcement actions (such as investigations, fines, penalties, audits, and inspections), additional reporting obligations, restrictions on processing sensitive information (including personal data), litigation (including class- action claims), financial liabilities to third parties, indemnification responsibilities, negative publicity, reputational damage, diversion of monetary funds, operational disruptions (including data availability), financial losses, and other similar harms. Security incidents and their associated consequences may disrupt our operations significantly and potentially lead to material program disruptions. For instance, the loss of clinical trial or nonclinical study data for our product candidates could cause delays in regulatory approval efforts and substantially increase costs due to the additional time and resources required for data recovery, verification, or potential reproduction. Our contractual agreements may lack adequate limitations of liability, and even when present, there is no guarantee that these provisions sufficiently shield us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot definitively

ascertain that our insurance coverage will adequately protect us or mitigate liabilities arising from our privacy and security practices. The availability of such coverage on commercially reasonable terms remains uncertain, as does its ability to cover future claims. Our employees or consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. ~~We are~~ **The Company is** exposed to the risk of employee fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards ~~we have~~ **the Company has** established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. ~~We have~~ **The Company has** adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions ~~we~~ **the Company take** to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and ~~we are~~ **the Company is** not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions, including civil, criminal or administrative. ~~36~~ **We** **The Company** may not successfully manage our growth. Our success will depend upon the effective management of our growth, which will place a significant strain on our management and on administrative, operational, and financial resources. To manage this growth, ~~we~~ **the Company** will be required to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. Our inability to manage this growth could have a material adverse effect on our business, financial condition, and results of operations.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY **If the Company is unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to our product candidates, and our ability to successfully commercialize any product candidates the Company may develop, and our science may be adversely affected.** As with our competitors, our ability to maintain and solidify a proprietary position for our product candidates will depend upon our success in obtaining effective patent claims that cover such product candidates, their manufacturing processes, and their intended methods of use, and enforcing those claims once granted. Furthermore, in some cases, ~~we~~ **the Company** may not be able to obtain issued claims covering our product candidates which are sufficient to prevent third parties, such as our competitors, from either utilizing our technology or designing around any patent claims to avoid infringing them. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, and results of operations. ~~Changes~~ **40** **Changes** in either the patent laws or their interpretation in the US and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our issued patents. Additionally, ~~we~~ **the Company** cannot predict whether the patent applications ~~we~~ **the Company** or our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time-consuming, and complex, and ~~we~~ **the Company** may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that ~~we~~ **the Company** will fail to identify patentable aspects of our research and development output in time to file for or obtain patent protection. Although ~~we~~ **the Company** ~~enter~~ **enters** into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. If any licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised or even lost entirely. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be subject to challenges based on invalidity and / or unenforceability. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. Patents also have a limited lifespan. In the United States, subject to certain extensions that may be obtained in some cases, the natural expiration of a utility patent is generally 20 years from its earliest effective filing date, and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and services, ~~we~~ **the Company** may be open to competition. Further, if ~~we~~ **the Company** ~~encounter~~ **encounters** delays in our development efforts, the period of time during which ~~we~~ **the Company** could market our products and services under patent protection would be reduced. ~~37~~ **Periodic** ~~Periodic~~ maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the United States Patent and Trademark Office (the “USPTO”) and various government patent agencies outside of the US over the lifetime of our and our licensors’ patents and applications. The USPTO and various non-US government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process and after patent issuance. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are

situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market in that jurisdiction with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, and results of operations. ~~We~~ **The Company may be subject to claims challenging the inventorship of our patents and other intellectual property. The Company** may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, ~~we~~ **the Company** may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship of inventions covered by our or our licensors' patents, trade secrets or other intellectual property. If ~~we~~ **the Company** or our licensors fail in defending any such claims, in addition to paying monetary damages, ~~we~~ **the Company** may lose valuable intellectual property rights, such as exclusive ownership of, or rights or licenses to use, intellectual property that is important to our products. Even if ~~we~~ **the Company** and our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations. ~~The~~ **41The** degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, can be expensive or difficult to enforce, and may not adequately protect our business or permit us to maintain our competitive advantage. For example: · others may be able to make products that are similar to our product candidates or utilize similar science or technology but that are not covered by the claims of the patents that ~~we~~ **the Company** may own or license from our licensors or that incorporate certain research in our product candidates that is in the public domain; · ~~we~~ **the Company** , or our licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that ~~we~~ **the Company** or our licensors own now or in the future; · ~~we~~ **the Company** , or our licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; ~~38-~~ others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; · it is possible that our or our licensors' current or future pending patent applications will not lead to issued patents; · issued patents that ~~we~~ **the Company** or our licensors hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; · our competitors or other third parties might conduct research and development activities in countries where ~~we~~ **the Company** or our licensors do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; · ~~we~~ **the Company** may not develop additional proprietary product candidates that are patentable; · the patents of others may harm our business if, for example, ~~we~~ **the Company** or our licensors are found to have infringed those patents or if those patents serve as prior art to our or our licensors' patents which could potentially invalidate our or our licensors' patents; and · ~~we~~ **the Company** may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property, which could ultimately result in public disclosure of the intellectual property if the third party' s patent application is published or issues to a patent. Should any of these events occur, they could have a material adverse effect on our business, financial condition, and results of operations. There is a great deal of litigation concerning intellectual property in our industry, and ~~we~~ **the Company** or our licensors could become involved in litigation. Even if resolved in our or our licensors' favor, litigation or other legal proceedings relating to intellectual property claims may cause us or our licensors to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. ~~We~~ **The Company** may not have sufficient financial or other resources to adequately conduct or defend against such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than ~~we~~ **the Company** can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and ability to compete in the marketplace. ~~39We~~ **42The Company** may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. Some of our employees and consultants were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although ~~we~~ **try-the Company tries** to ensure that our employees do not use the proprietary information or know-how of others in their work for us, ~~we~~ **the Company** may be subject to claims that ~~we~~ **the Company** or our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Litigation may be necessary to defend against these claims. If ~~we~~ **the Company fail-fails** in defending any such claims, in addition to paying monetary damages, ~~we~~ **the Company** may lose valuable intellectual property rights or personnel. Even if ~~we~~ **are-the Company is** successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

RISKS RELATED TO OUR SECURITIES Our Common Stock may be delisted from the Nasdaq Capital Market if ~~we~~ **the Company** cannot maintain compliance with Nasdaq' s continued listing requirements. In order to maintain our listing on Nasdaq, ~~we~~ **are-the Company is** required to comply with the Nasdaq requirements, which includes maintaining a minimum bid price and a minimum public float. For example, ~~we~~ **are-the Company is** required to maintain a minimum bid price of \$ 1. 00 per share, and ~~we~~ **the Company** traded below that threshold regularly during and prior to our fiscal year ended August 31, 2021. On September 13, 2021, ~~we~~ **the Company** received a notice from Nasdaq stating that ~~we~~ **were-the Company was** not in compliance with Nasdaq Listing Rule 5450 (a) (1) (the " Minimum Bid Price Rule ") because our Common Stock failed to maintain a minimum closing bid price of \$ 1. 00 for 30 consecutive business days. This notice had no immediate effect on the

Nasdaq listing or trading of our Common Stock. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), ~~we were the Company was~~ afforded an initial period of 180 calendar days, or until March 14, 2022, to regain compliance with the Minimum Bid Price Rule. ~~We were~~ **The Company was** then afforded a second grace period of an additional 180 calendar days, or until September 12, 2022, to regain compliance with the Minimum Bid Price Rule. On August 24, 2022, ~~we~~ **the Company** received a formal notification via letter from Nasdaq confirming that ~~we~~ **the Company** had regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550 (a) (2), which requires that our Common Stock maintain a minimum bid price of at least \$ 1.00 per share, and that the matter is now closed. If ~~we are~~ **the Company is** unable to maintain compliance with Nasdaq's continued listing requirements in the future, delisting from the Nasdaq Capital Market or any Nasdaq market could make trading our Common Stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our stock, the sale or purchase of our stock would likely be made more difficult and the trading volume and liquidity of our stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our Common Stock as currency or the value accorded by other parties. Further, if ~~we are~~ **the Company is** delisted, ~~we~~ **the Company** would also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our Common Stock and the ability of our stockholders to sell our Common Stock in the secondary market. If our Common Stock is delisted by Nasdaq, our Common Stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our ~~common~~ **Common stock Stock**. ~~We~~ **The Company** cannot assure you that our ~~common~~ **Common stock Stock**, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the-counter quotation system. If our Common Stock is delisted, it may come within the definition of "penny stock" as defined in the Securities Exchange Act of 1934 as amended (the "Exchange Act") and would be covered by Rule 15g-9 of the Exchange Act. That Rule imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For transactions covered by Rule 15g-9, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written agreement to the transaction prior to the sale. Consequently, Rule 15g-9, if it were to become applicable, would affect the ability or willingness of broker-dealers to sell our securities, and accordingly would affect the ability of stockholders to sell their securities in the public market. These additional procedures could also limit our ability to raise additional capital in the future. ~~401F-43If we~~ **the Company sell/sells** securities in future financings our stockholders may experience immediate dilution and, as a result, our stock price may decline. ~~We~~ **The Company** may from time to time issue additional shares of Common Stock at a discount from the current market price of our Common Stock, including potential sales of our equity to ~~Lincoln Park~~ **an institutional investor** as described above. As a result, our stockholders would experience immediate dilution upon the purchase of any of our securities sold at such discount. In addition, as opportunities present themselves, ~~we~~ **the Company** may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or Common Stock. If ~~we~~ **the Company** ~~issue~~ **issues** Common Stock or securities convertible into Common Stock, our common stockholders could experience additional dilution and, as a result, our stock price may decline. **The price of our securities may be volatile, and you could lose all or part of your investment. Further, the Company does not know whether an active, liquid and orderly trading market will continue for our securities or what the market price of our securities will be and as a result it may be difficult for you to sell your shares of our securities.** Although our securities are listed on the Nasdaq Capital Market, an active, liquid, and orderly trading market for our securities may not continue, and you may not be able to sell your shares quickly or at the market price if trading in shares of our securities is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our securities and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our securities as consideration, which could have a material adverse effect on our business, financial condition, and results of operations. In addition, the trading price of our securities is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. ~~Shares of our Common Stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144 (i) which apply to a former "shell company."~~ Our stock may experience limited trading volume. Many of our securities will be subject to restrictions on transfer under the Securities Act and may not be transferred in the absence of registration or the availability of a resale exemption. In particular, in the absence of registration, such securities cannot be resold to the public until certain requirements under Rule 144 promulgated under the Securities Act have been satisfied, including certain holding period requirements and other requirements applicable to companies that have previously been a shell company. An investor may be unable to sell such securities at the time or at the price or upon such other terms and conditions as the investor desires, and the terms of such sale may be less favorable than might be obtainable because of a limited market, which may never develop. Until December 2017, ~~we were~~ **the Company was** deemed a "shell company" under applicable SEC rules and regulations because ~~we~~ **the Company** had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. Pursuant to Rule 144 promulgated under the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted (i) until at least 12 months have elapsed from the date on which our Current Report on Form 8-K reflecting our status as a non-shell company, was filed with the SEC; and (ii) unless at the time of a proposed sale, ~~we are~~ **the Company is** subject to the reporting requirements of Section 13 or 15 (d) of the Exchange Act and have filed all reports and other materials required to be filed by Section 13 or 15 (d) of the Exchange Act, as applicable, during the preceding 12 months (or for such shorter period that ~~we were~~ **the Company was** required to file such reports and materials), other than Form 8-K reports. ~~We are~~ **The Company is** currently subject to the reporting rules under the Exchange

Act and ~~expect~~ **expects** to remain subject to the reporting requirements under the Exchange Act. However, ~~even then, many of our stockholders may be forced to hold their shares of our Common Stock for at least that 12-month period before they are eligible to sell those shares, and even after that 12-month period,~~ sales may not be made under Rule 144 unless ~~we are~~ **the Company is** in compliance with other requirements of Rule 144. Further, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless ~~we~~ **the Company agree** ~~agrees~~ to register such securities under the Securities Act, which could cause us to expend significant time and cash resources. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions ~~we~~ **the Company** may seek to pursue in the future (although none are currently planned). The lack of liquidity of our securities ~~as a result of the inability to sell under Rule 144 for a longer period of time than a non-former shell company~~ could cause the market price of our securities to decline or make it difficult to establish a trading market in our shares. ~~41Certain~~ **44Certain** of the possible adjustments to the warrants may result in a deemed distribution from us to a beneficial owner of a warrant that will be taxable, even though the beneficial owner does not receive a corresponding distribution of cash. The exercise terms of the warrants may be adjusted in certain circumstances. An adjustment to the number of shares of Common Stock that will be issued on the exercise of the warrants or an adjustment to the exercise price of the warrants (or, in certain circumstances, a failure to make adjustments) may be treated as a taxable deemed distribution to a holder of the warrants, even if such holder does not receive any cash or other property in connection with the adjustment. Holders of the warrants should consult their professional tax advisors regarding the proper treatment of any adjustments to the warrants. Sales of our currently issued and outstanding stock may become freely tradable pursuant to Rule 144 and sales of such shares may have a depressive effect on the share price of our ~~common~~ **Common stock Stock**. Many of the outstanding shares of Common Stock are “restricted securities” within the meaning of Rule 144. As restricted securities, these shares may be resold only pursuant to an effective registration statement or under the requirements of Rule 144 or other applicable exemptions from registration under the Securities Act and as required under applicable state securities laws. Rule 144 provides, in part, that a non-affiliate who has held restricted securities for a period of at least six months may sell their shares of Common Stock. Under Rule 144, affiliates who have held restricted securities for a period of at least six months may, under certain conditions, sell every three months, in brokerage transactions, a number of shares that does not exceed the greater of 1 % of a company’s outstanding shares of Common Stock or the average weekly trading volume during the four calendar weeks prior to the sale. A sale under Rule 144 or under any other exemption from the Securities Act, if available, or pursuant to subsequent registrations of our shares of Common Stock, may have a depressive effect upon the price of our shares of Common Stock. ~~We do~~ **The Company does** not plan to declare or pay any dividends to our stockholders in the near future. ~~We have~~ **The Company has** not declared any dividends in the past, and ~~we do~~ **the Company does** not intend to distribute dividends in the near future. The declaration, payment and amount of any future dividends will be made at the discretion of our Board and will depend upon, among other things, the results of operations, cash flows and financial condition, operating and capital requirements, and other factors as our Board considers relevant. There is no assurance that future dividends will be paid, and if dividends are paid, there is no assurance with respect to the amount of any such dividend. ~~We~~ **The Company incur** ~~incurs~~ significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. As a public company, ~~we~~ **the Company** will continue to incur significant legal, accounting, and other expenses. ~~We are~~ **The Company is** subject to the reporting requirements of the Exchange Act, which will require, among other things, that ~~we~~ **the Company file** ~~files~~ with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes- Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq to implement provisions of the Sarbanes- Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act (the “Dodd- Frank Act”) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which ~~we~~ **the Company operate** ~~operates~~ our business in ways ~~we~~ **the Company** cannot currently anticipate. ~~42If~~ **45If** the listing requirements of the Nasdaq Capital Market divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, ~~we~~ **the Company expect** ~~expects~~ these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and ~~we~~ **the Company** may be required to incur substantial costs to maintain the same or similar coverage. ~~We~~ **The Company** cannot predict or estimate the amount or timing of additional costs ~~we~~ **the Company** may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our board committees, or as executive officers. Future changes in financial accounting standards or practices may cause adverse unexpected financial reporting fluctuations and affect reported results of operations. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way ~~we~~ **the Company conduct** ~~conducts~~ business. Our disclosure controls and procedures may not be effective to ensure that ~~we~~ **the Company make** ~~makes~~ all required disclosures. As a public reporting company, ~~we are~~ **the Company is** subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be

disclosed by us in reports ~~we the Company file files~~ or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. ~~We The Company believe believes~~ that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. ~~43Anti--~~ **Anti-** takeover provisions in our amended and restated articles of incorporation and bylaws, as well as provisions in Nevada law, might discourage, delay, or prevent a change of control of our company or changes in our management and, therefore, depress the trading price of our securities. Our amended and restated articles of incorporation, bylaws and Nevada law contain provisions that could have the effect of rendering more difficult or discouraging an acquisition deemed undesirable by our Board. Our corporate governance documents include provisions: **· classifying our board providing for a single class of directors (“ where each member of the Board ”) into three classes of directors with staggered** ~~shall serve for a one- year term and may be elected to successive~~ terms; **· authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our Common Stock;** **· limiting the liability of, and providing indemnification to, our directors, including provisions that require the company to advance payment for defending pending or threatened claims;** **· limiting the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;** **· requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our Board;** **· controlling the procedures for the conduct and scheduling of board and stockholder meetings;** **· limiting the determination of the number of directors on our board and the filling of vacancies or newly created seats on the board to our Board then in office;** and **· providing that directors may be removed by stockholders at any time.** ~~These 46These~~ provisions, alone or together, could delay hostile takeovers and changes in control or changes in our management. As a Nevada corporation, ~~we are the Company is~~ also subject to provisions of Nevada corporate law, including Section 78. 411, et seq. of the Nevada Revised Statutes, which prohibits a publicly- held Nevada corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last two years has owned, 10 % of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. 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 our stockholders could receive a premium for their Common Stock in an acquisition. Our business is subject to changing regulations related to corporate governance and public disclosure that have increased both our costs and the risk of noncompliance. Because our Common Stock and our public warrants are publicly traded, ~~we are the Company is~~ subject to certain rules and regulations of federal, state, and financial market exchange entities charged with the protection of investors and the oversight of companies whose securities are publicly traded. These entities, including the Public Company Accounting Oversight Board, the SEC and Nasdaq, have issued requirements and regulations and continue to develop additional regulations and requirements in response to corporate scandals and laws enacted by Congress, most notably the Sarbanes- Oxley Act of 2002. Our efforts to comply with these regulations have resulted in, and are likely to continue resulting in, increased general and administrative expenses and diversion of management time and attention from revenue- generating activities to compliance activities. Because new and modified laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. ~~44We are The Company is~~ a smaller reporting company, and ~~we the Company~~ cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our securities less attractive to investors. For as long as ~~we the Company continue continues~~ to be a smaller reporting company, ~~we the Company~~ may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements. ~~We The Company~~ cannot predict if investors will find our securities less attractive because ~~we the Company~~ may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities, and our stock price may be more volatile. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline. The trading market for our securities will depend on the research and reports that securities or industry analysts publish about us or our business. ~~We do The Company does~~ not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable or fair- balanced coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, ~~we the Company~~ could lose visibility in the financial markets, which could cause our share price or trading volume to decline. **47**