**Risk Factors Comparison 2024-03-26 to 2023-03-22 Form: 10-K**

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

~~You should consider carefully the~~ **Investing in our common stock involves a high degree of** ~~risks~~ **risk. We have** described below **a number of uncertainties and risks that** , **in addition to uncertainties and risks presented elsewhere in this Annual Report, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below** as well as ~~the~~ **those** ~~other information~~ **presented elsewhere** in this Annual Report ~~on Form 10- K, before deciding whether to purchase, hold~~ **should be considered carefully when evaluating us,** ~~or sell shares of our common stock. The occurrence of any of the following risks could harm~~ our business ~~, financial condition, results of operations~~ and ~~/~~ **the value of** ~~or~~ **our** ~~growth prospects~~ **securities. On September 1, 2023, we announced that we had entered into the Giiant License Agreement with Giiant** ~~or~~ **for** ~~cause our actual results to differ materially from those~~ -- **the exclusive worldwide license** ~~contained in forward- looking statements we have made in this report and those we may make from time~~ to **Giiant** ~~time. You should consider all of the factors described as well as the other information in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes and " Management~~ ' s **assets** ~~Discussion and Analysis of Financial Condition and Results of Operations " when evaluating our business~~ . **As a** ~~If any of the following risks occur, our business, financial condition, results~~ - **result** ~~of operations and future growth prospects could be materially and adversely affected. In these circumstances~~ , **we changed** ~~the market price of our common stock could decline, and you may lose all or part of your~~ - **our strategic focus** ~~investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations~~ . Risks Related to **our** ~~the Company' s~~ Development, Commercialization and Regulatory Approval of **our** ~~the Company' s~~ Investigational Therapies **Our** ~~The Company' s~~ business depends on the successful **pre- clinical and** clinical development, regulatory approval **,** and commercialization of ~~LB1148~~ **our recently licensed therapeutic compound, including our lead asset PALI- 2108** . ~~The success of~~ **On September 1, 2023, we announced that we had entered into** the ~~Company~~ **Giiant License Agreement, pursuant to which we licensed all of Giiant** ' s current ~~business~~ **and future technologies, including PALI- 2108. PALI- 2108 is a pre- clinical asset and is our only asset being actively developed. Our success** depends on the ~~successful~~ development ~~, regulatory approval and commercialization~~ of ~~LB1148~~ **PALI- 2108** , **which** ~~as well as the Company' s ability to secure sufficient capital to fund its~~ - **is subject to** ~~business operations. The clinical and commercial success of LB1148 depends on~~ a number of ~~factors~~ **risks** , including ~~the following~~ : • **the continued enforceability of our research collaboration and license agreement with Giiant; • the** successful completion of ~~required clinical trials, including those trials not yet initiated, which may be significantly slower or~~ **our** ~~costlier than the Company currently anticipates~~ **IND or CTA enabling studies and research** ; • the ~~Company' s~~ **submission and approval of an IND or CTA; • our** ability to develop **and implement clinical** trial designs and protocols; • ~~whether~~ the ~~FDA~~ **successful initiation and completion of** ~~or~~ **our planned pre- clinical** ~~similar foreign regulatory agencies will require the Company to conduct additional~~ studies **and clinical trials** ~~beyond those currently planned~~ ; • **the** approval by the FDA **or other regulatory authority** to commence the marketing of ~~LB1148~~ **our product candidates** ; • the ~~Company~~ **ability for us** and third- **parties** ~~party contractors~~ , if applicable, **to** ~~achieving~~ **achieve** and ~~maintaining~~ --- **maintain** compliance with ~~their~~ **our** contractual obligations and ~~with~~ applicable regulatory requirements; • the ability of **our** ~~the Company' s~~ contract manufacturers to manufacture sufficient supply of ~~LB1148~~ **our product candidates** to meet the required **pre- clinical studies and** clinical trial ~~and commercial~~ supplies; • the ability of **our** ~~the Company' s~~ contract manufacturers to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing facilities and processes that are compliant with cGMP; • **our** ~~the Company' s~~ ability to obtain favorable labeling for ~~LB1148~~ **our product candidates** through regulators that allows for successful commercialization; • acceptance by physicians, insurers ~~and~~ **,** payors, and patients of the **beneficial** quality, ~~benefits,~~ safety and efficacy of ~~LB1148~~ **our product candidates** , if approved, including relative to alternative and competing treatments; • **our** ability to price ~~LB1148~~ **our product candidates** to recover **our** ~~the Company' s~~ development costs **and applicable milestone or royalty payments,** and generate a satisfactory profit margin; and • **our** ~~the Company' s~~ ability and ~~its~~ **our applicable collaboration and licensing** partners' ability to establish and enforce intellectual property rights **related** ~~in and~~ to ~~LB1148~~ **our product candidates and technologies** . If **we do** ~~the Company does~~ not achieve one or more of these factors, many of which are beyond ~~its~~ **our** control, in a timely manner or at all, **we** ~~the Company~~ could experience significant delays or an inability to obtain regulatory approvals or commercialize ~~LB1148~~ **our proposed product candidate** . Such delays may result in increased costs and the failure to complete ~~such trial~~ **any required regulatory activity** . Even if regulatory approvals are obtained, **we** ~~the Company~~ may never be able to successfully commercialize ~~LB1148~~ **our product candidates** . Accordingly, **we** ~~the Company~~ cannot make assurances that ~~it~~ **we** will ever be able to generate sufficient revenue through the sale of ~~LB1148, or~~ any ~~other future~~ product candidates, if approved, to internally fund ~~its~~ **our** business. There are **substantial risks inherent in drug development, and, as a result, we may** ~~no~~ **not** ~~FDA~~ **be able to successfully develop PALI** - ~~approved therapies for LB1148~~ **2108. Our research and development efforts are focused on a therapeutic based on PDE4 inhibitors. Our development of PALI- 2108 is in the early stages. However, such technology** ' s ~~lead~~ **commercial feasibility and acceptance in our target** indication ~~which~~ **of inflammatory bowel disease are unknown. Scientific research and development requires significant amounts of capital and** ~~makes~~ **takes a long time to reach commercial viability, if** it ~~difficult~~ **can be achieved at all. During the research and development process, we may experience technological barriers that we may be unable** to ~~predict~~ **overcome. Further, certain underlying premises in our development programs have not been proven. Because of** ~~the~~ **these** ~~timing, costs~~ and **similar uncertainties, it** ~~regulatory approval path of LB1148. The~~

~~Company' s lead indication for LB1148~~ is ~~the reduction~~ **possible that** ~~or~~ **our** ~~elimination of postoperative intra- abdominal adhesions. While there are multiple medical devices approved for the reduction or elimination of postoperative intra- abdominal adhesions, there are no approved drugs for such indication. The regulatory approval process for novel~~ product candidates **will not reach** ~~such as LB1148 can be more uncertain, expensive, and take longer than for other, better known or extensively studied therapeutic approaches. The development and~~ commercialization ~~strategy~~ **. If we are unable to successfully develop and commercialize our product candidates, we will be unable to generate revenue** ~~for~~ **or build a sustainable or profitable business. We depend on our license agreement with Giiant to permit us to use patents and patent applications relating to PALI- 2108. Termination of** ~~the~~ **these** ~~Company' s~~ **rights or the failure to comply with obligations under this agreement could materially harm our business and prevent us from developing or commercializing PALI- 2108, our** lead product candidate ~~LB1148 depends, in~~ **. We are a** ~~part~~ **party** ~~, on published scientific literature and the FDA' s prior findings regarding the safety and efficacy of tranexamic acid. If the Company is not able~~ to **a license agreement with Giiant under which we have been granted rights** ~~pursue this strategy, it may be delayed in receiving regulatory approval. The Hatch- Waxman Act added Section 505 (b) (2)~~ to **patents** ~~the U. S. Federal Food, Drug, and Cosmetic Act (" FDCA "). Section 505 (b) (2) permits the submission of an~~ **and patent applications** ~~NDA where at least some of the information required for approval comes from investigations~~ that **are important to** ~~were not conducted by or~~ **our business** ~~for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted~~ . **We** ~~The FDA interprets Section 505 (b) (2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature and / or the FDA' s previous findings of safety and efficacy for an approved product. The FDA also requires companies to perform additional clinical trials or measurements to support any deviation from the previously approved product and to justify that it is scientifically appropriate to~~ rely on ~~the applicable published literature~~ **this license agreement to be able to use various proprietary technologies that are material to** ~~or~~ **our business** ~~referenced product~~ , ~~referred to as bridging~~ **including certain trade secrets and patent applications that cover PALI- 2108** . ~~Although it~~ **Our rights to use this intellectual property and employ the inventions claimed in these patent applications and contained in the trade secrets are subject to the continuation of and our compliance with the terms of our license agreement. If we fail to comply with any of our obligations under the license agreement with Giiant, Giiant may have the right to terminate the license agreement, in which event we would not be able to continue the development of PALI- 2108. Additionally, disputes may arise under the license agreement regarding the intellectual property that** is **subject** ~~not required~~ to **such license agreement. If disputes over intellectual property that we have licensed** , ~~the FDA may approve the new product candidate for~~ **or in** ~~all or some of~~ the ~~indications~~ **future may license, prevent** ~~for~~ **or impair our ability to maintain** ~~which the referenced product has been approved, as well as for~~ any **of** ~~new indication sought by the Section 505 (b) (2) applicant, if such approval is supported by study data. The labeling, however, may be required to include all or~~ **our license agreements** ~~some of the limitations, contraindications, warnings or precautions or restrictions~~ on **acceptable terms** ~~use included in the reference product' s labeling~~ , **we** ~~including a boxed warning, or~~ may ~~require additional limitations, contraindications, warnings or precautions or restrictions on use. The Company currently plans to pursue marketing approval for LB1148, in the U. S. through a 505 (b) (2) NDA and will~~ be ~~completing bridging analyses prior to NDA submissions. If the FDA disagrees with the Company' s conclusions regarding the appropriateness of its reliance on the FDA' s prior findings of safety and efficacy for TXA or on published literature, or if the Company is not otherwise able to bridge to the listed drug or published literature to demonstrate that its reliance is scientifically appropriate, the Company could be required to conduct additional clinical trials or other studies to support its NDA, which could lead to unanticipated costs and delays or to the termination of the development program for LB1148. If the Company is~~ unable to ~~obtain approval for LB1148 through the 505 (b) (2) NDA process, it may be required to pursue the more expensive and time consuming 505 (b) (1) approval process, which consists of full reports of investigations of safety and effectiveness conducted by or on the behalf of the Company. Notwithstanding the approval of a number of products by the FDA under Section 505 (b) (2), pharmaceutical companies and others have objected to the FDA' s interpretation of Section 505 (b) (2). If the FDA' s interpretation of Section 505 (b) (2) is~~ successfully **develop** ~~challenged, the FDA may be required to change its policies~~ and **commercialize** ~~practices with respect to Section 505 (b) (2) regulatory approvals, which could delay or even prevent the FDA from approving any NDA that the Company submits pursuant to the 505 (b) (2) process. Even if the Company is allowed to pursue the 505 (b) (2) regulatory pathway to FDA approval, there~~ -- **the affected** ~~is no assurance it that the Company' s~~ product candidates **and technologies** ~~will receive the requisite approvals for commercialization~~ . **Pre-** ~~The Company may find it difficult to enroll patients in its~~ clinical **and** ~~trials, which could delay or prevent it from proceeding with~~ clinical ~~trials of its product candidates. The Company' s inability to identify, qualify, and enroll patients in its clinical trials on a timely basis could result in the completion of the trials being delayed. Patient enrollment and trial completion are affected by numerous additional factors, including the: • process for identifying patients; • design of the trial protocol; • eligibility and exclusion criteria; • perceived risks and benefits of the product candidate under study; • availability of competing therapies and clinical trials; • severity of the disease under investigation; • proximity and availability of clinical trial sites for prospective patients; • ability to obtain and maintain patient consent; • risk that enrolled patients will drop out before completion of the trial; • patient referral practices of physicians; and • ability to monitor patients adequately during and after treatment. If the Company has difficulty enrolling a sufficient number of subjects to conduct its clinical trials as planned, it may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on its business, financial condition, results of operations and prospects. For example, the Company has recently paused enrollment in its Phase 3 study for return of bowel function. As a result, there can be no assurances that the Company will be able to complete that clinical trial, if it chooses to resume the study, on either a timely basis, or at all. Clinical~~ drug development is very expensive, time- consuming and uncertain. **The pre-** ~~Clinical~~ **clinical and clinical** development ~~new drug~~ **of product** candidates is very expensive, time- consuming, difficult to design and implement, and the outcomes are inherently uncertain. Most product

candidates that commence clinical trials are never approved by regulatory authorities for commercialization and of those that are approved , many do not cover their costs of development. In addition, we ~~the Company~~ , any partner with which ~~it~~ we may in the future collaborate, the FDA, or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, or institutional review boards ( ~~"~~ “ IRB ~~"~~ ” ) at our ~~the Company's~~ trial sites, may suspend, delay, require modifications to or terminate our ~~the Company's~~ clinical trials , once begun, at any time. We ~~The Company expects~~ expect that ~~its~~ our operations and ~~clinical trials~~ development of PALI- 2108 will require substantially more capital than ~~it~~ we currently ~~has~~ have , and we ~~the Company~~ cannot guarantee when or if ~~it~~ we will be able to secure such additional funding. We have ~~The Company has~~ historically funded ~~its~~ our operations ~~, including its past~~ and prior development efforts ~~present clinical trials,~~ through the sale of ~~its~~ our securities. Based on our ~~the Company's~~ existing cash resources and ~~its~~ our current or future plan of operations, we do ~~the Company may~~ not have adequate capital to ~~complete its current clinical trials or~~ fund our anticipated operations through ~~. Moreover, the Company cannot guarantee that its cash resources, even after giving effect to recent offerings, will be sufficient for it to complete~~ completion of ~~enrolling patients in both clinical trials and provide for~~ the development of PALI- 2108 ~~Company's working capital needs~~ . As a result, we ~~the Company~~ may need to secure additional ~~financing~~ funding . If we are ~~the Company is~~ not able to obtain financing in the future or on acceptable terms, we may have to curtail our research and development efforts as well as our operations. There can be no assurance that our product candidates will obtain regulatory approval. The sale of human therapeutic products in the U. S. and foreign jurisdictions is subject to extensive and time- consuming regulatory approval, which requires, among other things: • pre- clinical data required for the submission of an IND or CTA; • controlled research and human clinical testing; • establishment of the safety and efficacy of the proposed product candidate; • government review and approval of a submission containing manufacturing, pre- clinical and clinical data; and • adherence to cGMP regulations during production and storage. The proposed product candidate we currently have under development, PALI- 2108, will require significant development, pre- clinical and clinical testing and the investment of significant funds to gain regulatory approval before it ~~may have to terminate~~ can be commercialized. The results of ~~or~~ our ~~suspend one or both~~ research and human clinical testing of PALI- 2108 may not meet regulatory requirements. If approved, PALI- 2108 may also require the completion of post- market studies. There can be no assurance that PALI- 2108 will be successfully developed and approved. The process of completing pre- clinical and clinical testing and obtaining the required approvals is expected to take a number of years and require the use of substantial resources. Further, there can be no assurance that PALI- 2108 will be shown to be safe and effective in clinical trials ~~early and / or~~ receive applicable ~~curtail its operations. The results of previous clinical trials may not be predictive of future results, and the results of the Company's current and planned clinical trials may not satisfy the requirements of the FDA or non- U. S.~~ regulatory ~~authorities~~ approvals . If we fail ~~The results from the prior preclinical studies and clinical trials of LB1148 may not necessarily be predictive of the results of future preclinical studies or clinical trials. Even if the Company is able~~ to obtain regulatory approvals ~~complete its planned clinical trials of its product candidates according to its current development timelines , the results from prior preclinical and clinical trials of its product candidates may not be replicated in these future trials. Many companies in the pharmaceutical and biotechnology industries (including those with greater resources and experience) have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development, and the Company cannot be certain that~~ it will not ~~face similar setbacks~~ be able to market PALI- 2108 and our operations may be adversely affected . If pre- ~~These setbacks have been caused by, among other things, preclinical --~~ clinical ~~findings made while~~ and clinical studies of PALI- 2108 do not yield successful results, then we may not continue to develop PALI- 2108. We must demonstrate that PALI- 2108 is safe and efficacious in humans through extensive pre- clinical and clinical testing. Our research and development programs are at an early stage of development. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any products, including the following: • the results of pre- clinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials ; • ~~were underway or~~ safety ~~or~~ and efficacy ~~observations made~~ results attained in early human clinical trials, if approved ~~including previously unreported adverse events. Moreover , preclinical and clinical data~~ may not be indicative of results that are obtained ~~often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily~~ in later ~~preclinical studies and~~ clinical trials ~~nonetheless~~ ; • after reviewing test results, we may abandon projects that it previously believed to be promising; • we or our regulators may suspend or terminate our clinical trials because the participating subjects or patients are being exposed to unacceptable health risks; and • PALI- 2108 may not have the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved. It may take us longer than we estimate to complete pre- clinical studies and clinical trials, and we may not be able to complete them at all. Although for planning purposes we project the commencement, continuation and completion of our pre- clinical studies and clinical trials; a number of factors, including scheduling conflicts with participating researchers and / or clinicians and research or clinical institutions, and difficulties in identifying or enrolling patients who meet trial eligibility criteria, may cause significant delays. We may not commence or complete pre- clinical studies or clinical trials involving PALI- 2108 as currently contemplated or may not be able to conduct them successfully. Even if our clinical studies are successful and achieve regulatory approval, the approved product label may be more limited than we anticipate, which could limit the commercial prospects of PALI- 2108. At the time therapeutic drugs are approved for marketing, they are given a “ product label ” from the FDA or other regulatory body. In most countries this label sets forth the approved indication for marketing, and identifies potential safety concerns for prescribing physicians and patients. While we intend to seek as broad a product label as possible for PALI- 2108, we may receive a narrower label than is expected by either us or third parties, such as stockholders and securities analysts. For example, any approved products may only be indicated to treat refractory patients (i. e., those who have

failed **some** ~~to obtain FDA approval. If the~~ **other** ~~Company fails~~ **first- line therapy). Similarly, it is possible that only a specific sub- set of patients safely responds** to ~~produce positive~~ **PALI- 2108. As a** ~~results~~ **result, even if successful** in ~~its~~ clinical trials **, PALI- 2108 could be approved only for a subset** of **patients. Additionally, safety considerations may result in contraindications that could further limit the scope of** ~~any~~ **an approved product label. Any** of **these or other safety and efficacy considerations could limit the commercial prospects of PALI- 2108. Even if PALI- 2108 is approved for commercialization, future regulatory reviews or inspections may result in** its ~~product candidates~~ **suspension or withdrawal** , ~~the development timelines,~~ **closure of a facility or substantial fines. If** regulatory ~~approvals~~ **approval** ~~, and commercialization prospects for~~ **to sell PALI- 2108** ~~its~~ **is** ~~product candidates~~ **received, regulatory agencies will subject PALI- 2108** , as well as the **manufacturing facilities** ~~Company' s business and financial prospects~~ , **to continual review** ~~would be adversely affected. Further, the Company' s product candidates may not be approved even if they achieve their respective primary endpoints in Phase 3 registration studies. The FDA or non- U. S. regulatory authorities may disagree with the Company' s trial designs or its interpretation of data from preclinical studies and clinical trials. The Company has taken the position that LB1148 has a single active ingredient, TXA. LB1148 also contains polyethylene glycol 3350 (" PEG "). Across different countries and different circumstances, PEG may be regulated as an~~ **and periodic inspection** ~~inactive ingredient, a medical device, or an active ingredient. There is uncertainty about (1) whether regulatory agencies will classify LB1148 as a fixed- combination drug product and (2) consequential implications of, for example, FDA' s fixed- combination drug product regulation concerning the evaluation of each active drug component' s individual contribution to the overall treatment effect. The treatment of PEG and any regulatory requirements, if it is considered an active ingredient, may differ across regulatory authorities~~ . If ~~LB1148 is considered a fixed- combination drug product, then this may impact the design and overall number of required clinical trials as well as additional requirements for nonclinical studies. Even though we are proceeding with a clinical trial for LB1148 as a single active ingredient drug product, we may be required to conduct additional trials, which could include the use of a factorial design, and nonclinical studies if, for example, FDA (1) concludes that PEG is an active ingredient in LB1148 and (2) is unwilling to provide a waiver from meeting their fixed- combination drug product regulation / requirements. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or another regulatory authority. Furthermore, any of these regulatory authorities may also approve the Company' s product candidate for fewer or more limited indications than it requests or may grant approval contingent on the performance of costly post- marketing clinical trials. If the clinical development of LB1148 is successful, the Company intends to eventually seek regulatory approvals of LB1148 initially in the U. S. and may seek approvals in other geographies. Before obtaining regulatory approvals for the commercial sale of any product candidate for any target indication, the Company must demonstrate to the FDA that the product candidate is safe and effective for use for the target indication. The Company cannot assure you that the FDA or non- U. S. regulatory authorities would consider its planned clinical trials to be sufficient to serve as the basis for approval of its product candidates for any indication. The FDA and non- U. S. regulatory authorities retain broad discretion in evaluating the results of the Company' s clinical trials and in determining whether the results demonstrate that its product candidates are safe and effective. The Company' s product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post- approval regulatory action. Unforeseen side effects from LB1148 could arise either during clinical development or, if approved, after it has been marketed. Undesirable side effects could cause the Company, any partners with which the Company may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Any of these occurrences may have an adverse material effect on the Company' s business, financial condition, operating results and prospects. Additionally, if the Company or others identify undesirable side effects, or other~~ previously unknown problems **with** ~~, caused by~~ a product ~~after obtaining U. S.~~ or ~~foreign~~ **manufacturing and laboratory facility are discovered, or we fail to comply with applicable** regulatory approval **requirements** , a ~~number of potentially negative consequences could result, including the FDA~~ **regulatory agency may impose restrictions on PALI- 2108 or us. The agency may** ~~requiring~~ **require** the **withdrawal of PALI- 2108** ~~Company to recall the product, which could prevent the Company or its potential partners~~ from **the** ~~achieving or maintaining~~ market ~~acceptance~~ **, closure** of the **facility or** ~~product and could substantially~~ -- **substantial fines** ~~increase the costs of commercializing such product~~ . **We** ~~The Company~~ may in the future conduct clinical trials for ~~its product candidates~~ **PALI- 2108** outside the United States, and the FDA ~~and~~ **or** applicable foreign regulatory authorities may not accept data from such trials. **We** ~~The Company, as well as investigator sponsors, have conducted clinical trials, is conducting clinical trials, and~~ may in the future choose to conduct ~~one or more~~ clinical trials outside of the U. S. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the U. S. or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions or exclusion. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U. S. population and U. S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time- consuming and delay aspects of **our** ~~the Company' s~~ business plan. **We anticipate relying** ~~The Company may rely~~ on third-

party CROs and other third parties to conduct and oversee ~~its~~ **our pre- clinical studies and** clinical trials. If these third parties do not meet **our** ~~the Company' s~~ requirements or otherwise conduct the **studies or** trials as required, **we** ~~the Company~~ may not be able to satisfy ~~its~~ **our** contractual obligations or obtain regulatory approval for, or commercialize, ~~its~~ **our** product candidates. **We** ~~The Company~~ may rely on third- party CROs to conduct and oversee ~~its LB1148~~ **our anticipated pre- clinical studies and** clinical trials and other aspects of product development. **We** ~~The Company~~ also ~~expects~~ **expect** to rely on various medical institutions, clinical investigators and contract laboratories to conduct ~~its~~ **our** trials in accordance with **our** ~~the Company' s~~ clinical protocols and all applicable regulatory requirements, including the FDA' s regulations and good clinical practice (" GCP ") requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties are expected to play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. **We** ~~The Company expects~~ **expect** to rely heavily on these parties for the execution of ~~its~~ **our** clinical trials and **pre-** ~~preclinical~~ **clinical** studies and will control only certain aspects of their activities. **We** ~~The Company~~ and ~~its~~ **our** CROs and other third- party contractors will be required to comply with GCP and good laboratory practice (" GLP ") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If **we** ~~the Company~~ or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal noncompliance from an audit or inspection, ~~the~~ **any** clinical data generated in **our** ~~the Company' s~~ clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require **us** ~~the Company~~ to perform additional clinical trials before approving ~~the Company' s or~~ **our or our** ~~the Company' s~~ partners' marketing applications. **We** ~~The Company~~ cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine whether or not any of **our** ~~the Company' s~~ clinical or **pre-** ~~preclinical~~ **clinical** trials comply with applicable GCP and GLP requirements. In addition, **our** ~~the Company' s~~ clinical trials generally must be conducted with ~~product~~ **compounds** produced under cGMP regulations. **Our** ~~The Company' s~~ failure to comply with these regulations and policies may require it to repeat clinical trials, which would be costly and delay the regulatory approval process. If any of **our** ~~the Company' s~~ CROs **were to** ~~or clinical trial sites~~ terminate their involvement ~~in one of~~ **with us,** ~~the~~ **there is** ~~Company' s clinical trials for any reason, the Company may not~~ **no assurance that we would** be able to enter into arrangements with alternative CROs or ~~clinical trial sites or~~ do so on commercially reasonable terms. **The successful commercialization of PALI- 2108, if approved, will depend in part on the extent to which government authorities and health insurers establish adequate reimbursement levels and pricing policies. Sales of any approved drug candidate will depend in part on the availability of coverage and reimbursement from third- party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Accordingly, coverage and reimbursement may be uncertain. Adoption of any drug by the medical community may be limited if third- party payers will not offer coverage. Additionally, significant uncertainty exists as to the reimbursement status of newly approved drugs. Cost control initiatives may decrease coverage and payment levels for any drug and, in turn, the price that we will be able to charge and / or the volume of our sales. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers. Any denial of private or government payer coverage or inadequate reimbursement could harm our business or future revenues, if any. If we partner with third parties with respect to any of our product candidates, we may be reliant on that partner to obtain reimbursement from government and private payors for the drug, if approved, and any failure of that partner to establish adequate reimbursement could have a negative impact on our revenues and profitability.** In addition, ~~if~~ **both** the ~~Company' s~~ **federal and state governments in the United States and foreign governments continue to propose and pass new legislation,** ~~relationship~~ **regulations** ~~with clinical trial sites is terminated~~ **, and policies affecting coverage and reimbursement rates, which are designed** ~~it may experience the loss of patient follow- up information unless the Company is able~~ to ~~transfer~~ **contain or reduce** the **cost of health** care ~~of~~ **. Further federal and state proposals and healthcare reforms are likely, which could limit** ~~those~~ **the prices that can be charged** ~~patients to another qualified clinical trial site. In addition, principal investigators~~ for the ~~Company' s clinical trials may serve as scientific advisors or consultants to it from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA. Even if the Company receives marketing approval for LB1148, or any future product candidate, it may not be able to successfully commercialize its~~ product candidates ~~due to unfavorable pricing regulations~~ **that we develop and may further limit** ~~or~~ **our** ~~third- party~~ **commercial opportunity. There may be future changes that result in reductions in potential** coverage and ~~reimbursement policies, which could make it difficult for the Company to sell its product candidates profitably. Obtaining coverage and reimbursement approval for a product from a government or other third- party payor is a time consuming and costly process that could require the Company to provide supporting scientific, clinical and cost effectiveness data to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim~~ reimbursement levels for ~~new~~ **our** ~~products~~ **product candidates** , if **approved** ~~applicable, may also not be sufficient to cover costs~~ and **commercialized** ~~may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used~~ , ~~may be based on reimbursement levels already set for lower cost products~~ and **we cannot predict** ~~may be incorporated into existing payments for~~

other -- **the scope of** services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws **changes or the impact that those changes would have on our operations. If future reimbursement for PALI- 2108, subject to approval, are substantially less than projected, or rebate obligations associated with them are substantially greater than expected, our future net revenue and profitability, if any, could be materially diminished. We face potential product liability exposure, and if successful claims are brought against us, it may incur substantial liability for a product candidate and may have to** limiting --- **limit** drug prices **our commercialization. The use of our product candidates in clinical trials** and **the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us** by any future relaxation **clinical trial participants, consumers, health- care providers, pharmaceutical companies, or others selling our products. If we cannot successfully defend ourselves against these claims, it may incur substantial liabilities. Regardless** of **merit or eventual outcomes** laws that presently restrict imports of **such claims,** product **liability claims** from countries where they may **result** be sold at lower prices than in **: • decreased demand for our product candidates; • impairment of our business reputation; • withdrawal of clinical trial participants; • costs of litigation; • substantial monetary awards to patients or** the **other** United States **claimants; and • loss of revenues** . **Our** There is significant uncertainty related to the insurance coverage and **may not be sufficient to** reimbursement ---- **reimburse** of newly approved products **it for all expenses or losses it may suffer** . **Moreover, insurance** Third- party payors often rely upon Medicare coverage **policy is becoming increasingly expensive** and payment limitations in setting reimbursement policies , **in** but also have their -- **the** own methods and approval process apart from Medicare **future, we may not be able to maintain insurance** coverage **at** and reimbursement determinations. Coverage and reimbursement by a **reasonable** third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost - effective; and • neither experimental nor - **or in sufficient amounts to protect** investigational. The Company cannot be sure that coverage and reimbursement will be available for any product that it **against losses** commercializes and, if coverage and reimbursement are available, what the level of reimbursement will be. Reimbursement may impact the demand for, and the price of, any product for which the Company obtains marketing approval. The Company' s inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved products that the Company develops could have a material adverse effect on its operating results, its ability to raise capital needed to commercialize products and its overall financial condition . Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success. The commercial success of LB1148 **our product candidates** , if approved, will depend significantly on attaining broad adoption and use of the drug by physicians and patients. The degree and rate of physician and patient adoption of a product, if approved, will depend on a number of factors, including but not limited to: • patient demand for approved products that treat the indication for which they are approved; • the effectiveness of a product compared to other available therapies or treatment regimens; • the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors; • the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients; • insurers' willingness to see the applicable indication as a disease worth treating; • proper administration by physicians or patients; • patient satisfaction with the results, administration and overall treatment experience; • limitations or contraindications, warnings, precautions or approved indications for use different than those sought by **us** the Company that are contained in the final FDA- approved labeling **, or other authoritative regulatory body approved labeling,** for the applicable product; • any FDA requirement **, or other authoritative regulatory body requirement,** to undertake a risk evaluation and mitigation strategy; • the effectiveness of **our** the Company' s sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts; • adverse publicity about a product or favorable publicity about competitive products; • new government regulations and programs, including price controls and / or limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct- to- consumer advertising of pharmaceuticals; and • potential product liability claims or other product- related litigation. If LB1148 is **any of our product candidates are** approved for use but fails - **fail** to achieve the broad degree of physician and patient adoption necessary for commercial success, **our** the Company' s operating results and financial condition will be adversely affected, which may delay, prevent or limit its **our** ability to generate revenue and continue **our business. We have entered into a collaborative research agreement with Giiant related to pre- clinical development, which will require the efforts of Giiant and** its **personnel, which are out of our control. The license agreement with Giiant provides for certain joint research and development of PALI- 2108 related to pre- clinical studies and development. Our** business **strategy relies on such collaboration** . The Company' s product candidates, if approved, may face significant competition and their failure to **shorten** compete effectively may prevent them - **the** from achieving significant market penetration. The pharmaceutical industry is characterized by rapidly advancing **time required to file and IND and accelerate the knowledge transfer of trade secrets and other know- how associated with the licensed** technologies **. Overall** , **the success of the development PALI- 2108 will depend** intense competition, less effective patent terms, and a strong emphasis on **our ability** developing newer, fast- to - market proprietary therapeutics. Numerous companies **manage such relationship, and to a certain extent, to the efforts of Giiant, which** are **beyond** engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that the Company is developing, including LB1148. The Company will face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies, medical device companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, regulatory expertise, clinical trial expertise, intellectual property portfolios, more international reach, experience in obtaining patents and regulatory approvals for product candidates and other resources than the Company. Some of the companies that offer competing products also have a broad range of other product offerings,

~~large direct sales forces and long- term customer relationships with the Company' s target physicians, which could inhibit the Company' s market penetration efforts. The inability of the Company' s products, if approved, to effectively compete with such products could adversely affect the Company' s results and operations. Any adverse developments related to LB1148 that occur during the clinical trials being conducted by Newsoara could affect the Company' s ability to obtain regulatory approval or~~ **our control** ~~commercialize LB1148. Newsoara has the rights to develop and commercialize LB1148 in China for return of bowel function, reduction of adhesions, and sepsis. If serious adverse events occur with respect to Newsoara' s clinical trials related to LB1148, the FDA and other regulatory authorities may delay, limit or deny approval of LB1148 or require the Company to conduct additional clinical trials as a condition to marketing approval, which would increase our costs and delay our ability to seek marketing approval. If the Company receives FDA approval for LB1148 and a new and serious safety issue is identified in connection with Newsora' s clinical trials related to LB1148, the FDA and other regulatory authorities may withdraw their approval of the product or otherwise restrict the Company' s ability to market and sell LB1148. In addition, treating physicians may be less willing to administer the Company' s product due to concerns over such adverse events, which would limit the Company' s ability to commercialize LB1148 and would adversely affect the Company' s prospects and business~~ . Risks Related to **our** ~~the Company' s~~ Business **We have** ~~The Company has~~ a ~~very~~ limited operating history and ~~has~~ **have** never generated any revenues from product sales. **We are** ~~The Company is~~ a ~~clinical- stage~~ biopharmaceutical company with a ~~very~~ limited operating history that may make it difficult to evaluate the success of ~~its~~ **our** business to date and to assess ~~its~~ **our** future viability. **We were** ~~The Company was~~ initially formed in 2001 and ~~its~~ **our** operations, to date, have been limited to business planning, raising capital ~~, developing LB1148~~ and other research and development **activities related to our product candidates** . **We have** ~~The Company has~~ not yet demonstrated an ability to successfully complete any clinical trials and has never completed the development of any product candidate, nor has it ever generated any revenue from product sales or otherwise. Consequently, **we have** ~~the Company has~~ no meaningful operations upon which to evaluate ~~its~~ **our** business, and predictions about ~~its~~ **our** future success or viability may not be as accurate as they could be if it had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. **Our business model assumes revenue from, among other activities, marketing or out- licensing the products we develop. PALI- 2108 is in the early stages of development and because we have a short development history with PALI- 2108, there is a limited amount of information about us upon which you can evaluate our business and prospects. We have no approved drugs and thus have not begun to market or generate revenues from the commercialization of any products. We recently in- licensed PALI- 2108 and accordingly, we only have a limited history upon which we can evaluate our ability to develop PALI- 2108 as it is still at an early stage of development. Thus, we have limited experience and have not yet demonstrated our ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan, we will need to: • Execute product development activities using unproven technologies; • Build, maintain, and protect a strong intellectual property portfolio; • Demonstrate safety and efficacy of our drug candidates in multiple human clinical studies; • Receive FDA approval and approval from similar foreign regulatory bodies; • Gain market acceptance for the development and commercialization of any drugs we develop; • Ensure our products are reimbursed by commercial and / or government payors at a rate that permits commercial viability; • Develop and maintain successful strategic relationships with suppliers, distributors, and commercial licensing partners; • Manage our spending and cash requirements as our expenses will increase in the near term if we add programs and additional pre- clinical and clinical trials; and • Effectively market any products for which we obtain marketing approval. If we are unsuccessful in accomplishing these objectives, we may not be able to develop our proposed products, raise capital, expand our business or continue our operations. We have received a delisting notification from the Nasdaq Stock Market based on our Bid Price being under $ 1. 00 for thirty (30) consecutive trading days. If we are not able to regain compliance with the applicable continued listing requirements or standards of** The ~~Company' s~~ **Nasdaq Capital Market, Nasdaq could delist our common stock. Our ability to publicly or privately sell equity securities and the liquidity of our** common stock could be **adversely affected if we are** delisted from the Nasdaq Capital Market **or** if **we are** ~~the Company is~~ unable to **transfer our listing to another stock market. In order to** maintain **this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a requirement to maintain a minimum bid price of our common stock of $ 1. 00 per share (" Minimum Bid Price Requirement "). On October 19, 2023, we received notice (the " Notice ") from the Nasdaq Stock Market LLC (" Nasdaq ") advising us that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the $ 1. 00 per share minimum required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550 (a) (2). Under Nasdaq Listing Rule 5810 (c) (3) (A), we have until April 16, 2024 to regain** compliance with **the Minimum Bid Price Requirement** ~~Nasdaq' s continued listing standards~~ . ~~The Company' s~~ **If at any time during this period the closing bid price of our** common stock is **at least $ 1** ~~listed on the Nasdaq Capital Market~~ . ~~There are~~ **00 for** a ~~number~~ **minimum** of **10 consecutive business days, we will regain compliance with the Minimum Bid Price Requirement and our common stock will** ~~continued~~ - **continue** ~~listing requirements that the Company must satisfy in order~~ to ~~maintain its~~ **be eligible for** listing on The Nasdaq Capital Market ~~, including~~ **absent noncompliance with any** ~~the~~ **other** requirement ~~to maintain a minimum bid price of at least $ 1. 00 (the " Bid Price Rule "). Although the Company is currently in compliance with the Bid Price Rule, the Company has been unable to comply with this rule in the past and~~ for ~~periods in 2022 the Company' s~~ continued listing ~~on~~ **. In the event that we do not regain compliance by April 16, 2024, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for** the Nasdaq Capital Market ~~required~~ **with** the ~~grant~~ **exception** of ~~a grace~~ **bid price, and we provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance** period **, by effecting** ~~from Nasdaq and the implementation~~

~~of~~ a ~~1- for- 50~~ reverse stock split **, if necessary** . If **we do not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We will** ~~the~~ **then** ~~Company fails~~ **be entitled** to **appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing. We cannot be sure that our share price will** comply with the ~~Bid Price Rule~~ **requirements for continued listing of our shares on the Nasdaq Capital Market** in the future ~~,~~ or ~~any of~~ **that it will comply with** the other continued listing requirements ~~, there can be no assurance that the Company will be able to regain compliance~~ . **Notwithstanding** ~~The delisting of the Company' s common stock would likely adversely affect the market liquidity and market price of the Company' s common stock and the Company' s ability to obtain financing for the continuation of the Company operations and / or result in the loss of confidence by investors. If the Company is unable to successfully retain and integrate a new management team~~ , **we** ~~the Company' s business could be adversely impacted. Effective October 11, 2022, the Company appointed its Chief Financial Officer, J. D. Finley, as its Interim Chief Executive Officer. Also effective October 11, 2022, Dr. Hallam and Dr. Dawson, the Company' s former CEO and CMO respectively, ceased providing services to the Company. On November 18, 2022 the Company announced the appointment of Herbert B. Slade, MD, FAAAAI as Chief Medical Officer of the Company. On February 8, 2023, the Company announced it had promoted Robert McRae to Chief Operating Officer. The Company' s success depends largely on the development and execution of its business strategy by its senior management team. The Company currently has a limited executive team with limited experience of working together. Additionally, the loss of any members or key personnel would likely harm the Company' s ability to implement its business strategy and respond to the rapidly changing market conditions in which it operates. There can be no assurance that the Company will be able to retain the current members of its management team. Moreover, there may be a limited number of persons with the requisite skills to serve in these positions, and the Company~~ cannot assure you that **, in the future, our securities will meet the continued listing requirements to be listed on Nasdaq. If our common stock is delisted by Nasdaq,** it **could lead** ~~will be able~~ to ~~identify~~ **a number of negative implications** , **including an adverse effect** ~~employ or retain such qualified personnel~~ on ~~acceptable terms~~ **the price of our common stock** , ~~if~~ **increased volatility in our common stock, reduced liquidity in our common stock, a limited availability of market quotations for our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker- dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell- side analysts and might deter certain institutions and persons from investing in our securities** at all. ~~The Company cannot~~ **Delisting could also cause a loss of confidence from our collaborators, vendors, suppliers and employees, which could harm our business and future prospects. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on the OTC Bulletin Board, OTCQB or another over- the- counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, our common stock. In addition, there can be no** ~~assure~~ **assurance** ~~you~~ that ~~management will succeed in working together as a team~~ **our common stock would be eligible for trading on any such alternative exchange or markets** . ~~In the event that the Company~~ **Moreover, if our common stock** is **delisted,** ~~unable to retain or integrate its~~ - **it** ~~management team~~ **may come within the definition of " penny stock " under the Exchange Act** , ~~its business, prospects,~~ **which imposes additional sales practice requirements on broker- dealers who sell securities to persons other than established customers** and **accredited investors** ~~operations could be adversely impacted~~ . ~~The Company currently has no products approved~~ **For example, we and / or broker- dealers are required to make a special suitability determination** for **purchases** ~~sale, and it may never obtain regulatory approval to commercialize any~~ of ~~its product candidates. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post- market information related to its biopharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities in the U. S. and in foreign countries, and~~ such **securities** ~~regulations differ from country to country~~ and **must receive** ~~frequently are revised. Even after the Company achieves U. S. regulatory approval for~~ a **purchaser** ~~product candidate, if at all, the Company will be subject to continued regulatory review and compliance obligations. A product candidate~~ ' s ~~approval may contain requirements~~ **written consent to the transaction prior to any purchase. Additionally, unless exempt, prior to a transaction involving a penny stock, the penny stock rules require the delivery of a disclosure schedule prescribed by the SEC relating to the penny stock market. The broker- dealer must also disclose the commissions payable to the broker- dealer, current quotations** for ~~potentially costly post- approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. The Company also will be subject to ongoing FDA obligations and continued regulatory review with respect to, among other~~ -- **the securities** ~~things, the manufacturing, processing, labeling, packaging, distribution, pharmacovigilance~~ and ~~adverse event reporting~~ , ~~storage, advertising, promotion and recordkeeping~~ **if the broker- dealer is the sole market- maker** for the ~~Company' s product candidates~~ **security, the fact that they are the sole market- maker and their presumed control over the market. Finally, monthly statements disclosing recent price information on the limited market in penny stocks must be sent to holders of such penny stocks** . These requirements ~~include submissions~~ **may reduce trading activity in the secondary market for our common stock and may impact the ability or willingness** of ~~safety~~ **broker- dealers to sell our securities, which could limit the ability of stockholders to sell their securities in the public market. We have received a notification from the Nasdaq Stock Market that our audit committee does not have three (3) independent members as a result of recent director resignations. If we fail to timely appoint** ~~and~~ - **an independent director that meets the Nasdaq Stock Market Requirements for audit committees, Nasdaq could delist our common stock. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from the Nasdaq Capital Market or if we are unable to transfer our listing to** ~~other~~ **another stock** ~~post- marketing~~ --- **market**

~~information and reports~~ **. In order to maintain this listing** , ~~registration,~~ **we must satisfy certain** continued **listing standards** ~~compliance with cGMP requirements and with the FDA' s GCP requirements and GLP requirements, which are regulations and guidelines enforced by the FDA for all of the Company' s product candidates in clinical and preclinical development, and for any clinical trials that it conducts post- approval, as well as continued compliance with the FDA' s laws governing commercialization of the approved product~~ , including but not limited to the ~~FDA~~ **composition of our Audit Committee. On March 22, 2024, we received a notice from Nasdaq stating that pursuant to the recent resignation of certain members of the Board of Directors (" Board"), we became noncompliant with the requirements set forth in Nasdaq Listing Rule 5605 (c) (2) (A), which requires us to have an audit committee of at least three (3) independent directors. We currently only have two (2) independent directors serving on the Audit Committee. The Notice states that, consistent with Nasdaq Listing Rule 5605 (c) (4), Nasdaq will provide us with a cure period in order to regain compliance (i) until the earlier of the Company** ' s ~~Office of Prescription Drug Promotion~~ **next annual shareholders' meeting or March 4, 2025, or** ( **ii** ~~" OPDP "~~ ) **if the next annual shareholders' meeting is held before September 3, 2024, then we must evidence compliance no later than September 3, 2024. If we do not** ~~regulation~~ ---- **regain** ~~of promotional activities~~ **compliance within the allotted compliance period** , ~~fraud and abuse~~ **including any extensions that may be granted by Nasdaq** , ~~product sampling~~ **Nasdaq will provide notice that our common stock will be subject to delisting. We will then be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing. We cannot be sure that we will be able to appoint a new director** , **with suitable experience and expertise to serve on our Audit Committee to comply with the requirements for continued listing of our shares on the Nasdaq Capital Market in the future or that we will be able to comply with the other continued listing requirements. Our success depends on attracting and retaining senior management and scientists with relevant expertise. Our future success depends to a significant extent on the continued services of our key employees, including our senior** scientific ~~speaker~~ **, technical and managerial personnel. We do not maintain key person life insurance for any of our executives and we do not maintain employment** ~~engagements~~ ---- **agreements** ~~and activities, formulary interactions as well as interactions~~ with ~~healthcare practitioners~~ **many senior employees** . ~~To~~ **Competition for qualified employees in** the **pharmaceutical industry** ~~extent that a product candidate~~ is **high** ~~approved for sale in other countries~~ , **and** ~~the Company may be subject to similar or~~ **our** ~~more onerous (i. e., prohibition~~ **ability to execute our strategy will depend in part** on ~~direct-~~ **our ability** to **continue to attract** ~~- consumer advertising that does not exist in the U. S.) restrictions~~ and **retain qualified scientists** ~~requirements imposed by laws~~ and **management** ~~government regulators in those countries~~ . **If we** ~~In addition, manufacturers of drug and biologic products and their facilities~~ are ~~subject~~ **unable** to **find** ~~continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If the Company or a regulatory agency discovers previously unknown problems with a product~~ , **hire and retain qualified individuals** ~~such as adverse events of unanticipated severity or frequency~~ , ~~or problems with the manufacturing, processing, distribution or storage facility where, or processes by which, the product is made, a regulatory agency may impose restrictions on that product or the Company, including requesting that the Company initiate a product recall, or requiring notice to physicians or the public, withdrawal of the product from the market, or suspension of manufacturing. If the Company, its~~ - **it will have difficulty implementing our business plan in a timely manner, or at all. We may choose to discontinue developing or commercializing any of our** product candidates **,** ~~or the manufacturing facilities for~~ - **or** ~~its~~ **may choose to not commercialize** product candidates ~~fail~~ **in approved indications, at any time during development or after approval, which could adversely affect us and our operations. At any time, we may decide to discontinue the development of, or temporarily pause the development of, any of our product candidates then in existence, for a variety of reasons, including the appearance of new technologies that make our product candidates obsolete, competition from a competing product or changes in or failure** to comply with applicable regulatory requirements ~~, a regulatory agency may: • impose restrictions on the sale, marketing or manufacturing of the products, amend, suspend or withdraw product approvals or revoke necessary licenses; • mandate modifications to promotional and other product- specific materials or require the Company to provide corrective information to healthcare practitioners or in its advertising; • require the Company or its partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, penalties for noncompliance and, in extreme cases, require an independent compliance monitor to oversee the Company' s activities; • issue warning letters, bring enforcement actions, initiate surprise inspections, issue show cause notices or untitled letters describing alleged violations, which may be publicly available; • commence criminal investigations and prosecutions; • impose injunctions, suspensions or revocations of necessary approvals or other licenses; • impose other civil or criminal penalties; • suspend any ongoing clinical trials; • place restrictions on the kind of promotional activities that can be done; • delay or refuse to approve pending applications or supplements to approved applications filed by the Company or its potential partners; • refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States; • suspend or impose restrictions on operations, including costly new manufacturing requirements; or • seize or detain products or require the Company or its partners to initiate a product recall. The regulations, policies or guidance of the FDA and other applicable government agencies may change, and new or additional statutes or government regulations may be enacted, including at the state and local levels, which can differ by geography and could prevent or delay regulatory approval of the Company' s product candidates or further restrict or regulate post- approval activities. The Company cannot predict the likelihood, nature or extent of adverse government regulations that may arise from future legislation or administrative action, either in the United States or abroad~~ . If **we** ~~the Company is not able to achieve and maintain regulatory compliance, it may not be permitted to commercialize its product candidates, which would adversely affect its ability to generate revenue and achieve or maintain profitability. The Company currently has no marketing capabilities and no sales organization. If the Company is unable to establish sales and marketing capabilities on its own or through third parties, the Company will be unable to successfully commercialize its product candidates, if approved, or generate product revenue. The Company currently has no~~

marketing capabilities and no sales organization. To commercialize the Company's product candidates, if approved, in the U. S. and other jurisdictions, the Company must build its marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services, and the Company may not be successful in doing so. Although the Company's employees, consultants, contractors, and partners have experience in the marketing, sale and distribution of pharmaceutical products, and business development activities involving external alliances, from prior employment at other companies, the Company as a company has no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including its ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of the Company's internal sales, marketing, distribution and pricing / reimbursement / access capabilities would impact adversely the commercialization of these products. The Company may face product liability exposure, and if successful claims are brought against it, the Company may incur substantial liability if its insurance coverage for those claims is inadequate. The Company faces an inherent risk of product liability or similar causes of action as a result of the clinical testing of its product candidates. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority and notwithstanding the Company complying with applicable laws on promotional activity. The Company's products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with the Company's product candidates could result in injury to a patient or potentially even death. The Company cannot offer any assurance that it will not face product liability suits in the future, nor can it assure that its insurance coverage will be sufficient to cover its liability under any such cases. In addition, a liability claim may be brought against the Company even if its product candidates merely appear to have caused an injury. Product liability claims may be brought against the Company by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with its product candidates, among others, and under some circumstances even government agencies. If the Company cannot successfully defend itself against product liability or similar claims, it will incur substantial liabilities, reputational harm and possibly injunctions and punitive actions. In addition, regardless of merit or eventual outcome, product liability claims may result in: • withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants; • termination or increased government regulation of clinical trial sites or entire trial programs; • the inability to commercialize the Company's product candidates; • decreased demand for the Company's product candidates; • impairment of the Company's business reputation; • product recall or withdrawal from the market or labeling, marketing or promotional restrictions; • substantial costs of any related litigation or similar disputes; • distraction of management's attention and other resources from the Company's primary business; • significant delay in product launch; • substantial monetary awards to patients or other claimants against the Company that may not be covered by insurance; • withdrawal of reimbursement or formulary inclusion; or • loss of revenue. Although the Company has product liability insurance coverage for its clinical trials, the insurance coverage may not be sufficient to cover all of its product liability- related expenses or losses and may not cover it for any expenses or losses the Company may suffer. Moreover, insurance coverage is becoming increasingly expensive, restrictive and narrow, and, in the future, the Company may not be able to maintain adequate insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect it against losses due to product liability or other similar legal actions. The Company will need to increase its product liability coverage if any of its product candidates receive regulatory approval, which will be costly, and it may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all and for all geographies in which the Company wishes to launch. A successful product liability claim or series of claims brought against the Company, if judgments exceed its insurance coverage, could decrease its cash and harm its business, financial condition, operating results and future prospects. The Company's employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with whom the Company may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. The Company is exposed to the risk that its employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with which the Company may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless, gross or negligent misconduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; anticorruption laws, antikickback and Medicare / Medicaid rules, or laws that require the true, complete and accurate reporting of financial information or data, books and records. If any such or similar actions are instituted against the Company and the Company is not successful in defending itself or asserting the Company's rights, those actions could have a significant impact on the Company's business, including the imposition of civil, criminal and administrative and punitive penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, debarments, contractual damages, reputational harm, diminished profits and future earnings, injunctions, and curtailment or cessation of the Company's operations, any of which could adversely affect the Company's ability to operate the Company's business and the Company's operating results. The Company may be subject to risks related to off- label use of its product candidates. The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product's approved labeling. Although physicians may prescribe legally available drugs for off- label uses, manufacturers may not market or promote such uses. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, members of Congress and the public. Violations, including promotion of the Company's products for unapproved or off- label uses, are subject to enforcement

~~letters, inquiries and investigations, and civil, criminal and / or administrative sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by relevant foreign regulatory authorities. Even if the Company obtains regulatory approval for its product candidates, the FDA or comparable foreign regulatory authorities may require labeling changes or impose significant restrictions on a product' s indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. In the U. S., engaging in impermissible promotion of the Company' s product candidates for off- label uses can also subject it to false claims litigation under federal and state statutes, which can lead to civil, criminal and / or administrative penalties and fines and agreements, such as a corporate integrity agreement, that materially restrict the manner in which the Company promotes or distributes its product candidates. If the Company does not lawfully promote its products, the Company may become subject to such litigation and, if it is not successful in defending against such actions, those actions could have a material adverse effect on its business, financial condition and operating results and even result in having an independent compliance monitor assigned to audit the Company' s ongoing operations for a lengthy period of time. The Company' s or third party' s clinical trials may fail to demonstrate the safety and efficacy of its product candidates, or serious adverse or unacceptable side effects may be identified during their development, which could prevent or delay marketing approval and commercialization, increase the Company' s costs or necessitate the abandonment or limitation of the development of the product candidate. Before obtaining marketing approvals for the commercial sale of any product candidate, the Company must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidate is both safe and effective for use in the applicable indication. Failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and are associated with side effects or have characteristics that are unexpected. Based on the safety profile seen in clinical testing, the Company may need to abandon development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more tolerable from a risk- benefit perspective. The FDA or an IRB may also require that the Company suspend, discontinue, or limit clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for the product candidate. Many pharmaceutical candidates that initially showed promise in early- stage testing and which were efficacious have later been found to cause side effects that prevented further development of the drug candidate and, in extreme cases, the side effects were not seen until after the drug was marketed, causing regulators to remove the drug from the market post- approval. The Company may expend its limited resources to pursue a particular indication and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success. Because the Company has limited financial and managerial resources, it is currently focusing only on development programs that it identifies for specific indications for its product candidates. As a result, the Company may forego or delay pursuit of opportunities for other indications, or with other potential product candidates that later prove to have greater commercial potential. The Company' s resource allocation decisions may cause it to fail to capitalize on viable commercial products or profitable market opportunities. The Company' s spending on current and future research and development programs for specific indications or future product candidates may not yield any commercially viable products. If the Company does not accurately evaluate the commercial potential or target market for a product candidate, it may not gain approval or achieve market acceptance of that candidate, and its business and financial results will be harmed. The Company may choose to discontinue developing or commercializing any of its product candidates, or may choose to not commercialize product candidates in approved indications, at any time during development or after approval, which could adversely affect the Company and its operations. At any time, the Company may decide to discontinue the development of, or~~ temporarily pause ~~the development of, any of its product candidates for~~ - **or** ~~a variety of reasons, including the appearance of new technologies that make its product candidates obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If the Company temporarily pauses or terminates~~ - **terminate** a program in which ~~it has~~ **we have** invested significant resources, **we** ~~the Company~~ will not receive any return on ~~its~~ **our** investment and ~~it~~ **we** will have missed the opportunity to have allocated those resources to potentially more productive uses **,** which could have an adverse effect on **us** ~~the Company~~ and ~~its~~ **our** business. **Our** ~~The Company may also be subject to stricter healthcare laws, regulation and enforcement, and its failure to comply with those laws could adversely affect its business, operations and financial condition. Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to the Company' s business. The Company is subject to regulation by both the federal government and the states in which it or its partners conduct business. The healthcare laws and regulations that may affect the Company' s ability to operate include, but are not limited to: the federal Anti- Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act; the federal physician sunshine requirements under the Affordable Care Act; the Foreign Corrupt Practices Act as it applies to activities outside of the United States; and state law equivalents of many of the above federal laws. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of the Company' s business activities could be subject to challenge under one or more of such laws. In addition, healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti- Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Achieving and sustaining compliance with these laws may prove costly. In addition, any action against the Company for violation of these laws, even if the Company successfully defends against it, could cause the Company to incur significant legal expenses and divert its management' s attention from the operation of its business and result in reputational damage. If the Company' s operations are found to be in violation of any of the laws described above~~

~~or any other governmental laws or regulations that apply to the Company, it may be subject to significant penalties, including administrative, civil and criminal penalties, damages, including punitive damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of its operations, and injunctions, any of which could adversely affect the Company' s ability to operate its business and its financial results. The Company' s~~ inability to successfully in- license, acquire, develop and market additional product candidates or approved products ~~would~~ **could** impair ~~its~~ **our** ability to grow ~~its~~ **our** business. ~~The Company~~ **PALI- 2108 is currently our only product candidate being actively developed. We** may in- license, acquire, develop and market additional products and product candidates. **Since our** ~~Because the Company' s~~ internal research and development capabilities are limited, it may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to it. The success of this strategy depends partly on **our** ~~the Company' s~~ ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements. The process of identifying, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with **us** ~~the Company~~ for the license or acquisition of product candidates and approved products. Moreover, **we** ~~the Company~~ may devote resources to potential acquisitions or licensing opportunities that are never completed, or **we** ~~the Company~~ may fail to realize the anticipated benefits of such efforts. **We** ~~The Company~~ may not be able to acquire the rights to additional product candidates on terms that it finds acceptable or at all. Further, any product candidate that **we** ~~the Company acquires~~ **acquire** or licenses may require additional development efforts prior to commercial sale, including **pre-** ~~preclinical~~ --- **clinical** or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, **we** ~~the Company~~ cannot provide assurance that any approved products that it acquires will be manufactured or sold profitably or achieve market acceptance. **We** ~~The Company~~ may seek to avail ~~itself~~ **ourselves** of mechanisms to expedite the development or approval for product candidates it may pursue in the future, such as Fast Track or breakthrough designation, but such mechanisms may not actually lead to a faster development or regulatory review or approval process. **We** ~~The Company~~ may seek to avail ~~itself~~ **ourselves** of Fast Track designation, breakthrough designation, or priority review for product candidates it may pursue in the future. For example, if a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. However, the FDA has broad discretion with regard to these mechanisms, and even if **we** ~~the Company believes~~ **believe** a particular product candidate is eligible for any such mechanism, it cannot guarantee that the FDA would decide to grant it. Even if **we** ~~the Company believes~~ **believe** a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if it does obtain Fast Track or priority review designation or pursue an accelerated approval pathway, **we** ~~the Company~~ may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw a particular designation if it believes that the designation is no longer supported by data from **our** ~~the Company' s~~ clinical development program. Risks Related to **our** ~~the Company' s~~ Dependence on Third Parties **We** ~~The Company expects~~ **expect** to rely on collaborations with third parties for the successful development and commercialization of ~~its~~ **our** product candidates. **We** ~~The Company expects~~ **expect** to rely upon the efforts of third parties for the successful development and commercialization of **our** ~~the Company' s current and future~~ product candidates. The clinical and commercial success of **our** ~~the Company' s~~ product candidates may depend upon maintaining successful relationships with third- party partners **,** which are subject to a number of significant risks, including the following: • **our** ~~the Company' s~~ partners' ability to execute their responsibilities in a timely, cost- efficient and compliant manner; • reduced control over delivery and manufacturing schedules; • price increases; • manufacturing deviations from internal or regulatory specifications; • quality incidents; • the failure of partners to perform their obligations for technical, market or other reasons; • misappropriation of ~~the Company' s current or~~ **our** ~~future~~ product candidates; and • other risks in potentially meeting **our** ~~the Company' s current and future~~ product commercialization schedule or satisfying the requirements of ~~its~~ **our** end- users. **We** ~~The Company~~ cannot provide **any** assurance that ~~it~~ **we** will be able to establish or maintain third- party relationships in order to successfully develop and commercialize ~~its~~ **our** product candidates. ~~The Company relies~~ **We anticipate relying** completely on third- party contractors to supply, manufacture and distribute clinical drug supplies for ~~its~~ **our** product candidates. **We do** ~~The Company does~~ not currently have, nor ~~does it~~ **do we** plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute **pre-** ~~preclinical~~ --- **clinical** , clinical or commercial quantities of drug substances or products. Additionally, **we have** ~~the Company has~~ not entered into a long- term commercial supply agreement to provide ~~it~~ **us** with such drug substances or products. As a result, **our** ~~the Company' s~~ ability to develop ~~its~~ **and commercialize, if approved, our** product candidates is dependent **on our** ~~, and the Company' s~~ ability to ~~supply its products commercially will depend, in part, on the Company' s ability to~~ obtain the ~~active pharmaceutical ingredients (" APIs ")~~ and other substances and materials used in ~~its~~ **our** product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for **pre-** ~~preclinical~~ --- **clinical** and clinical testing and commercialization. If **we** ~~the Company fails~~ **fail** to develop and maintain supply and other technical relationships with these third parties, ~~it~~ **we** may be unable to continue to develop or commercialize ~~its~~ **our** products and product ~~candidate~~ **candidates** , which could adversely affect **us** ~~the Company~~ and ~~its~~ **our** business. **We are** ~~The Company is~~ dependent on ~~its~~ **our** contract suppliers and manufacturers for day- to- day compliance with applicable laws and ~~cGMPs~~ **cGMP** for production of **our proposed** ~~both APIs and finished~~ products **and API** . If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, **we** ~~the Company~~ may not be able to commercialize or obtain regulatory approval for the affected product or product ~~candidate~~

**candidates** successfully, and **we** ~~the Company~~ may be held liable for injuries sustained as a result. **We** ~~The Company expects~~ **expect** to continue to depend on third- party contract suppliers and manufacturers. **Our** ~~The Company' s~~ supply and manufacturing agreements do not guarantee that a contract supplier or manufacturer will provide services adequate for ~~its~~ **our** needs. Additionally, any damage to or destruction of ~~the Company~~ **our third- party manufacturers** ' ~~s third- party manufacturer' s~~ or suppliers' facilities or equipment, even by force majeure, may significantly impair **our** ~~the Company' s~~ ability to have ~~its~~ **our** products and product candidates manufactured on a timely basis. **Our** ~~The Company' s~~ reliance on contract manufacturers and suppliers further exposes ~~it~~ **us** to the possibility that they, or third parties with access to their facilities, ~~will have access to and~~ may misappropriate **our** ~~the Company' s~~ trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of **our** ~~the Company' s~~ suppliers may be located outside of the United States. This may give rise to difficulties in importing **our** ~~the Company' s~~ products or product candidates or their components into the United States or other countries. Risks Related to **Our** ~~the Company' s~~ Financial Operations **We have** ~~The Company has~~ expressed substantial doubt about ~~its~~ **our** ability to continue as a going concern. Management has determined that there is substantial doubt about **our** ~~the Company' s~~ ability to continue as a going concern for a period of one year following the issuance of this report. This determination was based on **conditions and events, considered in** the ~~following factors~~ **aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued, including** : (i) the ~~Company' s~~ **probability that significant changes to our anticipated level of operations, due to factors that are within or outside of our control, would cause our** available cash as of the date of this filing ~~will~~ **to** not be sufficient to fund ~~its~~ **our** anticipated level of operations for the next 12 months; **and** (ii) the **uncertainties** ~~Company will require additional financing by mid- 2024 to continue at its expected level~~ of ~~operations; and (iii) if~~ the **cost and timing of** ~~Company fails to obtain the needed capital, it will be forced to delay, scale back, or~~ **our** ~~eliminate some~~ **efforts to in- license** or **acquire a new product candidate** ~~all of its development activities or perhaps cease operations~~ . **Our** ~~The Company' s~~ future consolidated financial statements may include a similar qualification about ~~its~~ **our** ability to continue as a going concern. **Our** ~~The Company' s~~ year- end and interim consolidated financial statements were prepared assuming that it will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty. **If we** ~~The Company would need to~~ seek additional financing ~~or modify its operational plans. If the Company seeks additional financing~~ to fund ~~its~~ **our** business activities in the future and there remains substantial doubt about ~~its~~ **our** ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to **us** ~~the Company~~ on commercially reasonable terms or at all **. We have a history of net losses, and we expect to continue to incur net losses and may never achieve profitability. We have incurred net losses since our inception, including net losses of $ 12. 3 million and $ 14. 3 million for the years ended December 31, 2023 and December 31, 2022, respectively. We expect that our operating losses will continue for the foreseeable future as it continues our drug development and discovery efforts. To achieve profitability, we must, either directly or through licensing and / or partnering relationships, meet certain milestones, successfully develop and obtain regulatory approval for one or more drug candidates and effectively manufacture, market and sell any drugs we successfully develop. Even if we are able to successfully commercialize product candidates that receive regulatory approval, it may not be able to realize revenues at a level that would allow it to achieve or sustain profitability. Accordingly, we may never generate significant revenue and, even if it does generate significant revenue, it may never achieve profitability** . Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in **our** ~~the Company' s~~ consolidated financial statements. **Our** ~~The Company' s~~ management has identified a material weakness in ~~its~~ **our** internal control over financial reporting. The material weakness was due to a lack of controls in the financial closing and reporting process, including a lack of segregation of duties and the documentation and design of formalized processes and procedures surrounding the creation and posting of journal entries and account reconciliations. ~~Additionally, the Company' s management identified a material weakness in its internal control over the fair value calculation of options granted during the quarter ended June 30, 2021, although management concluded that this material weakness has been remediated in the year ended December 31, 2022.~~ If **our** ~~the Company' s~~ remaining material weakness, which management concluded is still present as of ~~December 31, 2022~~ **the date of these financial statements** , is not remediated, or if **we** ~~the Company identifies~~ **identify** further material weaknesses in ~~its~~ **our** internal controls, **our** ~~the Company' s~~ failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in ~~its~~ **our** consolidated financial statements and a failure to meet ~~its~~ **our** reporting and financial obligations. Changing circumstances and market conditions, some of which may be beyond **our** ~~the Company' s~~ control, could impair our ability to access our existing cash and cash equivalents and investments and to timely pay key vendors and others. Changing circumstances and market conditions, some of which may be beyond **our** ~~the Company' s~~ control, could impair ~~its~~ **our** ability to access ~~its~~ **our** existing cash and cash equivalents and investments and to timely pay key vendors and others. For example, on March 10, 2023, Silicon Valley Bank (" SVB") was placed into receivership with the Federal Deposit Insurance Corporation (" FDIC"), which resulted in all funds held at SVB being temporarily inaccessible by SVB' s customers. Although **we do** ~~the Company does~~ not have any funds at SVB, if other banks and financial institutions with whom **we have** ~~the Company has~~ banking relationships enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, **we** ~~the Company~~ may be unable to access, and **we** ~~the Company~~ may lose, some or all of ~~its~~ **our** existing cash and cash equivalents to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances **we** ~~the Company~~ might not be able to timely pay key vendors and others. **We** ~~The Company~~ regularly maintain cash balances that are not insured or are in excess of the FDIC' s insurance limit. Any delay in **our** ~~the Company' s~~ ability to access ~~its~~ **our** cash and cash equivalents (or the loss of some or all of such funds) or to timely pay key vendors and others could have a material adverse effect on **our** ~~the Company' s~~ operations and cause it to need to seek additional capital sooner than planned. **Risks Related to Our Intellectual Property We may not be**

**able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us. Our success with respect to our current and future product candidates will depend, in part, on our ability to obtain and maintain patent protection in both the U. S. and other countries, to preserve our trade secrets and to prevent third parties from infringing on our proprietary rights. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents around the world.** The ~~Company~~ **patent application process, also known as patent prosecution, is expensive and time- consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know- how or discover workarounds to our patents that would not constitute infringement. Any of these outcomes could impair our ability to enforce the exclusivity of any issued or pending patents we may have, which may have an adverse impact on our business, financial condition and operating results. Our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions especially across countries. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates or may not provide us with sufficient protection for our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over- the- counter pharmaceutical companies. In addition, we cannot guarantee that any patents or other intellectual property rights will be issued from any pending or future patent or other similar applications owned by or licensed to us. Even if patents or other intellectual property rights have issued or will issue, we cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. We do not have outstanding issued patents covering all of the recent developments in our technology and are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates are challenged, it could dissuade companies from collaborating with us to develop or threaten our ability to commercialize or finance our product candidates. The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the U. S., and** ~~may~~ **many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally. Proprietary trade secrets and unpatented know- how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know- how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or enforced by courts, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets and unpatented know- how will not otherwise become known, inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If our trade secrets are independently discovered, we would not be able to prevent their use and if we or our agents or representatives inadvertently disclose trade secrets and / or unpatented know- how, we may not be allowed to retrieve these trade secrets and / or unpatented know- how and maintain the exclusivity it previously held. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States, especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and even in launching an identical version of our product notwithstanding we have a valid patent in that country. Competitors may use our technologies in jurisdictions where we have not obtained patent protection, or produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement on infringing activities is inadequate or where we have no patents. These products may compete with our products, and our patents or other intellectual property rights may not prevent them from competing. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the U. S. Patent and Trade Office (" USPTO") and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign**

**governmental patent agencies require compliance with a number of procedures, including certain documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and / or timely pay a prosecution fee. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to enter the market, which would have an adverse effect on our business. If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. We have entered into an in- license agreement with respect to our lead product candidate, PALI- 2108. This license agreement imposes various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may terminate the license. The loss of such rights would materially adversely affect our business, financial condition, operating results and prospects. We may be subject to patent infringement claims, which could result in substantial costs, liabilities and prevent us from commercializing our potential products. Because the intellectual property landscape in the fields in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on third- party rights. If any patent infringement claims are brought against us, whether successful, we may incur significant expenses and divert the attention of our management and key personnel from other business concerns. This could negatively affect our results of operations and prospects. We cannot be certain that patents owned or licensed by us will not be challenged, potentially successfully, by others. In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our customers, licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of such claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of customers, licensees, and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, we may be unable to continue selling such products. We may be subject to claims that our officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers. As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that our employees or consultants have inadvertently or otherwise wrongfully used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome. Other Risks Related to Our Securities We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all. We will require substantial additional capital to fund our operations and conduct the costly and time- consuming research and development, pre- clinical studies, and clinical work necessary to pursue regulatory approval of product candidates. Our future capital requirements will depend upon a number of factors, including: the number and timing of product candidates in the pipeline; progress with and results from pre- clinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete pre- clinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit our ability to achieve our business objectives. If we raise additional funds through public or private equity sales of our securities, the terms of these securities may include liquidation or other preferences that adversely impact the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership percentage will be decreased. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we obtain additional funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders. Our common stock price may be highly volatile. Since the completion of the merger with Seneca Biopharma, Inc., on April 27, 2021, our stock price has been subject to significant fluctuation. Market prices for securities of biotechnology and other life sciences companies historically have been particularly**

**volatile and may be subject to large daily price swings. Some of the factors that may cause the market price of our shares to fluctuate include, but are not limited to: • failure of our product candidates to show safety and / or efficacy in our pre-clinical or clinical trials; • our ability to obtain timely regulatory approvals for our product candidates, and delays or failures to obtain such approvals; • the results of pre- clinical or clinical trials, including our decision to pause or terminate any such trials; • failure of our product candidates, if approved, to achieve commercial success; • the entry into, or termination of, or breach by partners of key agreements, including the Giiant License Agreement; • the initiation of, material developments in, or conclusion of any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others; • announcements of any financings; • announcements by commercial partners or competitors of new commercial products, clinical progress or the lack of, significant contracts, commercial relationships or capital commitments; • failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; and • the loss of key personnel. Moreover, the stock markets in general have experienced substantial volatility in the biotechnology industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of our shares. In the past, following periods of volatility in the market price of a company' s securities, shareholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. We take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors. As of June 30, 2023, the last business day of our most recently completed second fiscal quarter, our public float is less than $ 250 million and therefore, we qualify as a smaller reporting company under SEC rules. As a smaller reporting company, we can take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Such reduced disclosures in our SEC filings may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $ 250 million. In that event, we could still be a smaller reporting company if our annual revenues are below $ 100 million and we have a public float of less than $ 700 million. We do not anticipate paying any dividends in the foreseeable future. The current expectation is that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our shares will be your sole source of gain, if any, for the foreseeable future. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock is and will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event it does have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline. Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock. Future sales in the public market of shares of our common stock, including shares issued upon exercise of our outstanding stock options or warrants, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for it to raise additional capital. Our business could be negatively affected as a result of the actions of activist stockholders, and such activism could impact the trading value of our securities. Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our Board and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our Board could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our Board and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our Board or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability, which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our Board with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our Board and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business. Securities class action litigation could divert our management' s attention**

**and harm our business and could subject us to significant liabilities. The stock markets have from time- to- time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of life sciences and biotechnology companies. These broad market fluctuations may cause the market price of our common shares to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. Even if we are successful in defending claims that may be brought in the future, such litigation could result in substantial costs and may be a distraction to our management and may lead to an unfavorable outcome that could adversely impact our financial condition and prospects. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management. Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15 % of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our Board, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the Board, which is responsible for appointing the members of management. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of Nasdaq. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10- K filing for that year, as required by Section 404 of the Sarbanes- Oxley Act. This has required that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner. Our management identified a material weakness in our internal control over financial reporting. If we do not remediate this material weakness, or if we identify further material weaknesses in our internal controls, our failure to establish and maintain effective internal financial and accounting controls and procedures could result in material misstatements in our consolidated financial statements and a failure to meet our reporting and financial obligations. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate consolidated financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Our Board of Directors has broad discretion to issue additional securities, which might dilute the net tangible book value per share of our common stock for existing stockholders. We are entitled under our certificate of incorporation to issue up to 280, 000, 000 shares of common stock and 7, 000, 000 " blank check " shares of preferred stock. Shares of our blank check preferred stock provide our Board with broad authority to determine voting, dividend, conversion, and other rights. As of December 31, 2023, we had outstanding, common stock or securities convertible into common stock, totaling 9, 270, 894 shares. As a result, we are authorized to issue up to an additional 270, 729, 106 shares of common stock or common stock equivalents under our certificate of incorporation as amended. Additionally, pursuant to the initial issuance of (i) 1, 000, 000 shares of Series A 4. 5 % Convertible Preferred Stock, of which 200, 000 shares are outstanding and (ii) 1, 460 shares of Series B Convertible Preferred Stock, of which no shares are outstanding, we are authorized to issue up to an additional 6, 800, 000 shares of preferred stock. We expect that significant additional capital may be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our existing shareholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to existing shareholders. Pursuant to our equity incentive plans and employee stock purchase plan, management is authorized to grant stock options, restricted stock units and other equity- based awards to employees, directors and consultants, and to sell common stock to employees, respectively. Any increase in the number of shares outstanding as a result of the exercise of outstanding options, the vesting or settlement of outstanding stock awards, or the purchase of shares pursuant to the employee stock purchase plan will cause shareholders to experience additional dilution, which could cause our stock price to fall. General Risk Factors Our business could** be adversely affected by ~~natural disasters and other~~ -- **the effects of health pandemics or epidemics,** ~~catastrophic events and by man- made problems~~ such as ~~terrorism~~ **the COVID- 19 pandemic, which could cause significant disruptions in our operations and those of our current or future CMOs, CROs, and other third parties upon whom we rely. Health pandemics or epidemics, such as the COVID- 19 pandemic, have in the past and could again in the future result in quarantines, stay- at- home orders, remote work policies, or other similar events** that **may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-**

**party manufacturing facilities or the availability or cost of materials, which** could disrupt ~~its business~~ **our supply chain. Moreover, our trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators, and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our trial** operations **. Disruptions or restrictions on our ability to travel to monitor data** ~~, and its business continuity and disaster recovery plans may not adequately protect it~~ from ~~a serious disaster. The Company~~ **our trials, or to conduct trials, or the ability of patients enrolled in our trials or staff at trial sites to travel, as well as temporary closures of our trial partners and CMOs** ~~'s headquarters and main research facility~~ **facilities** ~~are located in the greater San Diego area~~, **would negatively impact our trial activities** ~~which in the past has experienced severe earthquakes and fires~~. **In addition** ~~If these earthquakes~~, ~~fires~~ **we rely on independent clinical investigators** , **CROs, and** other ~~natural disasters~~ **third- party service providers to assist us in managing** , **monitoring, and otherwise carrying out certain of our preclinical studies and clinical trials, including the collection of data from our trials, and the effects of** health pandemics or epidemics, ~~terrorism~~ **such as the COVID- 19 pandemic, may affect their ability to devote sufficient time** and ~~similar unforeseen events beyond~~ **resources to our programs or to travel to** ~~its~~ **sites** ~~control~~ **to perform work for us. Similarly, our trials could be delayed and / or disrupted. As a result, the expected timeline for data readouts** , including **incompleteness in data collection and analysis and other related activities, and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and adversely affect our business, financial condition, results of operations, and prospects. In addition, impact on the operations of the FDA or comparable foreign regulatory authorities could negatively affect our planned trials and approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated. Unstable economic and market conditions may have serious adverse consequences on our business, financial condition, and stock price. Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, bank failures, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability (** for example **, related to** the ongoing ~~COVID~~ **Russia** - ~~19 pandemic~~ **Ukraine and Israel- Hamas conflict). The financial institutions in which we hold our cash and cash equivalents are subject to risk of failure. For example** , ~~prevented~~ **recent events surrounding certain banks, including Silicon Valley Bank, First Republic Bank, and Signature Bank, created temporary uncertainty on their customers' cash deposits in excess of Federal Deposit Insurance Corporation limits prior to actions taken by governmental entities. While we do not expect any developments with any such banks to have a material impact on our cash and cash equivalents balance, expected results of operations, or financial performance for the foreseeable future, if further failures in financial institutions occur where we hold deposits, we could experience additional risk. Any such loss or limitation on our cash and cash equivalents would adversely affect our business. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve,** it ~~from using all or a significant portion of its headquarters or research facility, it~~ may ~~be~~ **make any necessary debt or equity financing more** difficult ~~or~~ , **more costly** ~~in certain cases~~ , ~~impossible for the Company to continue its business for a substantial period of time. The Company does not have a disaster recovery or business continuity plan in place~~ and **more dilutive** ~~may incur substantial expenses as a result of the absence or limited nature of the Company's internal or third- party service provider disaster recovery and business continuity plans, which, particularly when taken together with its lack of earthquake insurance, could have a material adverse effect on its business~~ . Furthermore, ~~integral parties in the Company's supply chain are operating from single sites, increasing their vulnerability to natural disasters or~~ **our stock price may decline due in part to** ~~other~~ -- **the volatility of the stock market** ~~sudden, unforeseen and severe adverse events. If such an~~ **and** ~~event were to affect its supply chain, it could have a material adverse effect on~~ the **general economic downturn** ~~Company's ability to conduct clinical trials, its development plans and its business~~ . If our information systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences. In the ordinary course of our business, ~~we~~ **it** may process, as defined above, proprietary, confidential, and sensitive data, including personal data (such as health- related patient data), intellectual property, and trade secrets (collectively, sensitive information). We may rely upon third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third- party providers of cloud- based infrastructure, employee email, CROs, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties. The risk of a security breach or disruption, particularly through cyber- attacks, cyber- intrusion, malicious internet- based activity, and online and offline fraud, are prevalent and have generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. These threats are becoming increasingly difficult to detect and come from a variety of sources, including traditional computer hackers, threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported

actors. Some actors now engage and are expected to continue to engage in cyber- attacks, 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 cyber- attacks 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 social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, natural disasters, terrorism, war, and telecommunication and electrical failures. Ransomware attacks, including by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent 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. Furthermore, ~~the COVID- 19 pandemic and~~ our remote workforce poses increased risks to our information technology systems and data, as ~~more~~ **most** of our employees work from home, utilizing network connections outside our premises. Any of the previously identified or similar threats could cause a security breach or disruption. While **we have** ~~the Company has~~ not experienced any such security breach or other disruption to date, if such an event were to occur, it could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information and cause interruptions in **our** ~~the Company' s~~ operations, including material disruptions of ~~its~~ **our** development programs and business operations. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security breaches and disruptions. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry- standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security breach or disruption has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of certain security breaches and disruptions. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom ~~we rely~~ **it relies** ) experience a security breach or other disruption, or are perceived to have experienced such events, we may experience adverse consequences, including: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. In particular, since **we** ~~the Company sponsors~~ **sponsor** clinical trials, any breach or disruption that compromises patient data and identities could generate significant reputational damage, which may affect trust in **us** ~~the Company~~ and our ability to recruit for future clinical trials. Additionally, the loss of clinical trial data from completed or future clinical trials could result in delays in **our** ~~the Company' s~~ regulatory approval efforts and significantly increase ~~its~~ **our** costs to recover or reproduce the data. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Furthermore, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. **Our** ~~The Company' s~~ business and operations would suffer in the event of system failures, cyber- attacks or a deficiency in **our** ~~its cyber- security~~ **cybersecurity** . Despite the implementation of security measures, **our** ~~the Company' s~~ internal computer systems **,** and those of ~~its~~ **our** current and future CROs and other contractors and consultants **,** are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Although **we have** ~~the Company has~~ not suffered any material incidents to date, the risk of a security breach or disruption, particularly through cyber- attacks or cyber- intrusion, including by computer hackers, foreign governments, and cyber- terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While **we have** ~~the Company has~~ not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in **our** ~~the Company' s~~ operations, it could result in a material disruption of ~~its~~ **our** development programs and ~~its~~ **our** business operations. In addition, since **we** ~~the Company sponsors~~ **sponsor** clinical trials, any breach that compromises patient data and identities causing a breach of privacy could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in **us** ~~the Company~~ to recruit for future clinical trials. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in **our** ~~the Company' s~~ regulatory approval efforts and significantly increase ~~its~~ **our** costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, **our** ~~the Company' s~~ data or applications or inappropriate disclosure of confidential or proprietary information, **we** ~~the Company~~ could incur liability and the further development and commercialization of ~~its~~ **our** products and product candidates could be delayed. ~~Risks Related to the Company' s Intellectual Property The Company may not be able to obtain, maintain or~~

enforce global patent rights or other intellectual property rights that cover its product candidates and technologies that are of sufficient breadth to prevent third parties from competing against the Company. The Company's success with respect to its product candidates will depend, in part, on its ability to obtain and maintain patent protection in both the U. S. and other countries, to preserve its trade secrets and to prevent third parties from infringing on its proprietary rights. The Company's ability to protect its product candidates from unauthorized or infringing use by third parties depends in substantial part on its ability to obtain and maintain valid and enforceable patents around the world. The patent application process, also known as patent prosecution, is expensive and time- consuming, and the Company and its current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that the Company or its current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of the Company's patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of its business. Moreover, the Company's competitors independently may develop equivalent knowledge, methods and know- how or discover workarounds to the Company patents that would not constitute infringement. Any of these outcomes could impair the Company's ability to enforce the exclusivity of its patents effectively, which may have an adverse impact on its business, financial condition and operating results. The Company's ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions especially across countries. Accordingly, rights under any existing patents or any patents the Company might obtain or license may not cover its product candidates or may not provide the Company with sufficient protection for its product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over- the- counter pharmaceutical companies. In addition, the Company cannot guarantee that any patents or other intellectual property rights will issue from any pending or future patent or other similar applications owned by or licensed to the Company. Even if patents or other intellectual property rights have issued or will issue, the Company cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide the Company with any significant protection against competitive products or otherwise be commercially valuable to the Company in every country of commercial significance that the Company may target. The Company's ability to obtain and maintain valid and enforceable patents depends on whether the differences between its technology and the prior art allow its technology to be patentable over the prior art. The Company does not have outstanding issued patents covering all of the recent developments in its technology and is unsure of the patent protection that it will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents the Company owns or licenses, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents the Company holds or pursues with respect to its product candidates is challenged, it could dissuade companies from collaborating with the Company to develop or threaten its ability to commercialize or finance its product candidates. The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the U. S., and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. If the Company encounters such difficulties in protecting or are otherwise precluded from effectively protecting its intellectual property in foreign jurisdictions, its business prospects could be substantially harmed, especially internationally. Proprietary trade secrets and unpatented know- how are also very important to the Company's business. Although the Company has taken steps to protect its trade secrets and unpatented know- how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or enforced by courts, that the Company would have adequate remedies for any breach, including injunctive and other equitable relief, or that its trade secrets and unpatented know- how will not otherwise become known, inadvertently disclosed by the Company or its agents and representatives, or be independently discovered by its competitors. If trade secrets are independently discovered, the Company would not be able to prevent their use and if the Company and its agents or representatives inadvertently disclose trade secrets and / or unpatented know- how, the Company may not be allowed to retrieve these trade secrets and / or unpatented know- how and maintain the exclusivity it previously held. The Company may not be able to protect its intellectual property rights throughout the world. Filing, prosecuting and defending patents on the Company's product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States, especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, the Company may not be able to prevent third parties from practicing its inventions in all countries outside the United States and even in launching an identical version of the Company's product notwithstanding the Company has a valid patent in that country. Competitors may use the Company's technologies in jurisdictions where it has not obtained patent protection to develop their own products, or produce copy products, and, further, may export otherwise infringing products to territories where the Company has patent protection but enforcement on infringing activities is inadequate or where the Company has no patents. These products may compete with the Company's products, and the Company's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patent holder's patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. In these situations, the royalty the court requires to be paid by the license holder

receiving the compulsory license is not calculated at fair market value and can be inconsequential, thereby disaffecting the patentholder's business. In these countries, the Company may have limited remedies if its patents are infringed or if the Company is compelled to grant a license to its patents to a third party, which could also materially diminish the value of those patents. This would limit its potential revenue opportunities. Accordingly, the Company's efforts to enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that the Company owns or licenses, especially in comparison to what it enjoys from enforcing its intellectual property rights in the United States. Finally, the Company's ability to protect and enforce its intellectual property rights may be adversely affected by unforeseen changes in both U. S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals. Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application. Obtaining and maintaining the Company's patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and its patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the U. S. Patent and Trade Office (" USPTO") and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and / or timely pay a prosecution fee. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If the Company or its licensors fail to maintain the patents and patent applications covering its product candidates for any reason, the Company's competitors might be able to enter the market, which would have an adverse effect on the Company's business. If the Company fails to comply with its obligations under its intellectual property license agreements, it could lose license rights that are important to its business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of its rights to the relevant intellectual property or technology or increase its financial or other obligations to its licensors. The Company has entered into in- license agreements with respect to certain of its product candidates. These license agreements impose various diligence, milestone, royalty, insurance and other obligations on the Company. From time to time, the Company may be delayed in various diligence or other obligations upon it. For example, the Company has experienced delays in meeting certain regulatory milestones related to clinical studies under its license agreements with the Regents of the University of California (" Regents"). If the Company fails to comply with these obligations, Regents or the respective licensors may terminate the license. The loss of such rights could materially adversely affect its business, financial condition, operating results and prospects. If the Company is sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay it from developing or commercializing its product candidates. The Company's commercial success depends on its ability to develop, manufacture, market and sell its product candidates and use its proprietary and licensed technologies without infringing the proprietary rights of third parties. The Company cannot assure that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U. S.- and foreign- issued patents and pending patent applications owned by third parties exist in the fields relating to its product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that its product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents and other intellectual property rights cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in the Company's fields across many countries, there may be a risk that third parties may allege they have patent rights encompassing the Company's product candidates, technologies or methods. In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by the Company's product candidates or proprietary technologies notwithstanding patents and licenses the Company may possess. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, the Company cannot be certain that others have not filed patent applications for technology covered by its own and in- licensed issued patents or its pending applications. The Company's competitors may have filed, and may in the future file, patent applications covering the Company's own product candidates or technology similar to the Company's technology. Any such patent application may have priority over the Company's own and in- licensed patent applications or patents, which could further require the Company to obtain rights to issued patents covering such technologies, which may mean paying significant licensing fees or the like. If another party has filed a U. S. patent application on inventions similar to those owned or in- licensed to us, the Company or, in the case of in- licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention. The Company may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that its product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch- Waxman Act or other countries' laws similar to the Hatch- Waxman Act. These lawsuits could claim that there are existing patent rights for such drug, and this type of litigation can be costly and could adversely affect its operating results and divert the attention of managerial and

technical personnel, even if the Company does not infringe such patents or the patents asserted against the Company is ultimately established as invalid. There is a risk that a court would decide that the Company is infringing the third party' s patents and would order the Company to stop the activities covered by the patents. In addition, there is a risk that a court will order the Company to pay the other party significant damages for having violated the other party' s patents. The occurrence of any of the foregoing could adversely affect the Company' s business, financial condition or operating results. The Company may be subject to claims that its officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers. As is common in the biotechnology and pharmaceutical industries, certain of the Company' s employees were formerly employed by other biotechnology or pharmaceutical companies, including its competitors or potential competitors. Moreover, the Company engages the services of consultants to assist us in the development of the Company' s product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including the Company' s competitors or potential competitors. The Company may be subject to claims that these employees and consultants or the Company has inadvertently or otherwise wrongfully used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although the Company has no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if the Company is successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to its management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome. Other Risks Related to the Company The Company will need to raise additional financing in the future to fund its operations, which may not be available to it on favorable terms or at all. The Company will require substantial additional capital to fund its operations and conduct the costly and time- consuming clinical trials necessary to pursue regulatory approval of LB1148 and any other product candidates. The Company' s future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. For example, the Company recently paused enrollment in its Phase 3 study for return of bowel function, and as a result, the necessary costs and timing of the study are currently uncertain. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit the Company' s ability to achieve its business objectives. If the Company raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely impact the rights of its common stockholders. Further, to the extent that the Company raises additional capital through the sale of common stock or securities convertible or exchangeable into common stock, its stockholders' ownership percentage in the Company will be diluted. In addition, any debt financing may subject the Company to fixed payment obligations and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish certain valuable intellectual property or other rights to its product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. Even if the Company were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to the Company or its stockholders. The COVID- 19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect the Company' s business and the Company' s financial results and could cause a disruption to the development of the Company' s product candidates. Public health crises, such as pandemics or similar outbreaks, could adversely impact the Company' s business. The impact of the COVID- 19 pandemic and the efforts to mitigate it, resulted in and will likely continue to result in disruptions to the global economy, as well as businesses and capital markets around the world. The Company experienced delays in its development activities as a result of the COVID- 19 pandemic, primarily due to temporary and partial shutdowns at certain of the Company' s CROs and trial sites that have since resumed operations, and due to governmental responses to the pandemic. Additionally, the emergence of new variants, which could prove resistant to existing vaccines, could again result in major disruptions to businesses and markets worldwide. The extent to which the COVID- 19 pandemic will continue to impact the Company' s operations or those of its consultants and collaborators, will depend on future developments, including the global macroeconomic effects of the virus. Global, market and economic conditions, including inflation, may negatively impact the Company' s business, financial condition and share price. Concerns over inflation, geopolitical issues, the U. S. financial markets, foreign exchange rates, capital and exchange controls, unstable global credit markets and financial conditions and the COVID- 19 pandemic, have led to periods of significant economic instability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, and increased unemployment rates. The Company' s general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly and more dilutive. In addition, there is a risk that one or more of our current or future service providers, manufacturers, suppliers and other partners could be negatively affected by difficult economic times, which could adversely affect the Company' s ability to attain our operating goals on schedule and on budget or meet our business and financial objectives. In addition, the Company faces several risks associated with international business and are subject to global events beyond its control, including war, public health crises, such as pandemics and epidemics, trade disputes, economic sanctions, trade wars and their collateral impacts and other international events. Any of these changes could have a material adverse effect on the Company' s reputation, business, financial condition or results of operations. There may be

changes to the Company' s business if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man- made disasters, including famine, flood, fire, earthquake, storm or disease. In February 2022, armed conflict escalated between Russia and Ukraine. The sanctions announced by the U. S. and other countries, following Russia' s invasion of Ukraine against Russia to date include restrictions on selling or importing goods, services or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business and financial organizations in Russia. The U. S. and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets, all of which could impact the Company' s business, financial condition and results of operations. The stock price of the Company may be highly volatile. The market price of shares of the Company could be subject to significant fluctuations. Since the completion of the Merger on April 27, 2021, the Company' s stock price has already been subject to significant fluctuation. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. Some of the factors that may cause the market price of shares of the Company to fluctuate include, but are not limited to: • the ability of the Company to obtain timely regulatory approvals for LB1148 or future product candidates, and delays or failures to obtain such approvals; • issues in manufacturing LB1148 or future product candidates; • the results of current and any future clinical trials of LB1148; • failure of the Company' s current and future product candidates, if approved, to achieve commercial success; • the entry into, or termination of, or breach by partners of key agreements, including key commercial partner agreements; • the initiation of, material developments in, or conclusion of any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others; • announcements of any dilutive equity financings; • announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments; • failure to elicit meaningful stock analyst coverage and downgrades of the Company' s stock by analysts; and • the loss of key personnel. Moreover, the stock markets in general have experienced substantial volatility in the biotech industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of the Company' s shares. In the past, following periods of volatility in the market price of a company' s securities, shareholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the Company' s profitability and reputation. The Company takes advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in its common stock being less attractive to investors. As of June 30, 2022, the last business day of the Company' s most recently completed second fiscal quarter, the public float of the Company is less than $ 250 million and therefore, the Company qualifies as a smaller reporting company under SEC rules. As a smaller reporting company, the Company is able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in its SEC filings. Decreased disclosures in the Company' s SEC filings due to its status as a smaller reporting company may make it harder for investors to analyze its results of operations and financial prospects. The Company cannot predict if investors will find the Company' s common stock less attractive if it relies on these exemptions. If some investors find its common stock less attractive as a result, there may be a less active trading market for its common stock and its stock price may be more volatile. The Company may take advantage of the reporting exemptions applicable to a smaller reporting company until it is no longer a smaller reporting company, which status would end once it has a public float greater than $ 250 million. In that event, the Company could still be a smaller reporting company if its annual revenues were below $ 100 million and it has a public float of less than $ 700 million. The Company does not anticipate paying any dividends in the foreseeable future. The current expectation is that the Company will retain its future earnings to fund the development and growth of its business. As a result, capital appreciation, if any, of the shares of the Company will be your sole source of gain, if any, for the foreseeable future. If the Company fails to attract and retain management and other key personnel, it may be unable to successfully develop or commercialize its product candidates or otherwise implement its business plan. The biotechnology industry has experienced a high rate of turnover in recent years. The Company' s ability to compete in the highly competitive biopharmaceuticals industry depends upon the ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. The Company will conduct its operations in the greater San Diego area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. The Company may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of the other biopharmaceutical companies against which the Company will compete have greater financial and other resources, different risk profiles and a longer history in the industry. The Company' s competitors may provide higher compensation, more diverse opportunities and / or better opportunities for career advancement. Any or all of these competing factors may limit the Company' s ability to continue to attract and retain high quality personnel, which could negatively affect its ability to successfully develop and commercialize its product candidates and to grow the business and operations as currently contemplated. The Company' s ability to use NOL carryforwards and certain other tax attributes may be limited. The Company has incurred substantial losses during its history and does not expect to become profitable in the near future, and it may never achieve profitability. Unused U. S. federal and state net operating loss (" NOL ") carryforwards generated in taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current U. S. federal income tax law, U. S. federal NOLs generated in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U. S. federal NOLs in taxable years beginning after December 31, 2020, is limited to 80 % of taxable income. State NOL

carryforward periods, expirations and limitations may differ from federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, (the" Code"), and corresponding provisions of state law, if the Company undergoes (or has undergone) an " ownership change, " which is generally defined as a greater than 50- percentage- point cumulative change, by value, in its equity ownership over a three- year period, the Company' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. Including the recently completed Merger, the Company has completed several equity offerings since its inception which may have resulted in an ownership change as defined by Sections 382 and 383 of the Code, or could result in an ownership change in the future. The Company has not completed a Code Section 382 and 383 analysis regarding the limitation of NOL and research and development credit carryforwards for all relevant tax years. Accordingly, the Company' s pre- 2018 NOL carryforwards may expire prior to being used, its NOL carryforwards generated in 2018 and thereafter will be subject to a percentage limitation and, the Company' s ability to use pre- change NOL carryforwards and other pre- change tax attributes (such as research tax credits) to offset post- change income or taxes may be limited. Similar provisions of state tax law may also apply to limit the Company' s use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if the Company attains profitability, it may be unable to use all or a material portion of its NOLs and other tax attributes, which could adversely affect future cash flows. Changes in tax law could adversely affect the Company' s business. The rules dealing with U. S. federal, state and local income taxation are constantly under review by the Internal Revenue Service, the U. S. Treasury Department and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect the Company or holders of its common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on the Company' s business, cash flow, financial condition or results of operations. Anti- takeover provisions in the Company' s charter documents and under Delaware law could make an acquisition of the Company more difficult and may prevent attempts by the Company stockholders to replace or remove the Company management. Provisions in the Company' s certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because the Company is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15 % of the outstanding Company voting stock from merging or combining with the Company. Although the Company believes these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with the Company' s Board, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the Company' s stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the Board, which is responsible for appointing the members of management. If the Company fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired. The Company is subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of Nasdaq. The Sarbanes- Oxley Act requires, among other things, that the Company maintain effective disclosure controls and procedures and internal control over financial reporting. The Company must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10- K filing for that year, as required by Section 404 of the Sarbanes- Oxley Act. This has required that the Company incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expend significant management efforts. The Company may experience difficulty in meeting these reporting requirements in a timely manner. The Company may discover weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its consolidated financial statements. Prior to the Merger, LBS' s management identified a material weakness in its internal control over financial reporting. The material weakness was due to a lack of controls in the financial closing and reporting process for LBS, including a lack of segregation of duties and the documentation and design of formalized processes and procedures surrounding the creation and posting of journal entries and account reconciliations. If the Company does not remediate this material weakness, or if the Company identifies further material weaknesses in its internal controls, the Company' s failure to establish and maintain effective internal financial and accounting controls and procedures could result in material misstatements in its consolidated financial statements and a failure to meet its reporting and financial obligations. If the Company is not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act, or if it is unable to maintain proper and effective internal controls, the Company may not be able to produce timely and accurate consolidated financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Our Board has broad discretion to issue additional securities, which might dilute the net tangible book value per share of our common stock for existing stockholders. The Company is entitled under its certificate of incorporation to issue up to 280, 000, 000 shares of common stock and 7, 000, 000 " blank check " shares of preferred stock. Shares of the Company' s blank check preferred stock provide its Board with broad authority to determine voting, dividend, conversion, and other rights. As of March 8, 2023, the Company has outstanding, common stock or securities convertible into common stock, totaling 4, 503, 977 shares. As a result, the Company is authorized to issue up to an additional 275, 496, 023 shares of common stock or common stock equivalents under its certificate of incorporation as amended. Additionally, pursuant to the initial issuance of (i) 1, 000, 000 shares of Series A 4. 5 % Convertible Preferred Stock, of which 200, 000 shares are outstanding and (ii) 1, 460 shares of Series B Convertible Preferred Stock, of which no shares are outstanding, the Company is authorized to issue up to an additional 6, 800, 000 shares of preferred stock. The Company expects that significant additional capital may be needed in the future to continue its planned operations. To the extent the Company raises additional capital by issuing equity securities, its existing shareholders may experience substantial dilution. The Company may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner the

Company determines from time to time. If the Company sells common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to the Company's existing shareholders, and new investors could gain rights superior to existing shareholders. Pursuant to the Company's equity incentive plans and employee stock purchase plan, management is authorized to grant stock options, restricted stock units and other equity- based awards to employees, directors and consultants, and to sell common stock to employees, respectively. Any increase in the number of shares outstanding as a result of the exercise of outstanding options, the vesting or settlement of outstanding stock awards, or the purchase of shares pursuant to the employee stock purchase plan will cause shareholders to experience additional dilution, which could cause the stock price to fall. General Risk Factors If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the Company, its business or its market, its stock price and trading volume could decline. The trading market for the Company's common stock is and will be influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts may elect not to provide research coverage of the Company's common stock, and such lack of research coverage may adversely affect the market price of its common stock. In the event it does have equity research analyst coverage, the Company will not have any control over the analysts, or the content and opinions included in their reports. The price of the Company's common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of the Company or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline. Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock. Future sales in the public market of shares of our common stock, including shares issued upon exercise of our outstanding stock options, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital. Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities. Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our Board and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our Board could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our Board and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our Board or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our Board with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our Board and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business. Securities class action litigation could divert our management's attention and harm our business and could subject us to significant liabilities. The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of life sciences and biotechnology companies. These broad market fluctuations may cause the market price of our ordinary shares to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharma companies have experienced significant stock price volatility in recent years. Even if we are successful in defending claims that may be brought in the future, such litigation could result in substantial costs and may be a distraction to our management and may lead to an unfavorable outcome that could adversely impact our financial condition and prospects. 57