Risk Factors Comparison 2025-03-24 to 2024-03-26 Form: 10-K

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

Investing in our common stock involves a high degree of risk. We have described below a number of uncertainties and risks that, in addition to uncertainties and risks presented elsewhere in this Annual Report **on Form 10- K** , may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Annual Report **on Form 10- K** should be considered carefully when evaluating us, our business and the value of our securities. ~~On September 1, 2023, we announced that we had entered into the Giiant License Agreement with Giiant for the exclusive worldwide license to Giiant' s assets. As a result, we changed our strategic focus.~~ Risks Related to ~~our~~ **Our** Development, Commercialization and Regulatory Approval of ~~our Investigational Therapies~~ **Our Product Candidates** Our business depends on the successful ~~pre- clinical and~~ clinical development, regulatory approval, and commercialization of our ~~recently licensed~~ therapeutic ~~compound~~ **compounds** , including our lead asset PALI- 2108. On ~~September~~ **October 9, 2024, Health Canada approved our Canadian Clinical Trial Application (" CTA ") to commence a Phase** 1 **clinical trial for** ~~, 2023, we announced that we had entered into the Giiant License Agreement, pursuant to which we licensed all of Giiant' s current and future technologies, including~~ PALI- 2108 **in Canada** . **On November 7, 2024, we commenced the Phase 1 clinical trial of** PALI- 2108 ~~is a pre- clinical asset and is our only asset being actively developed~~ . Our success depends on the development **and clinical success** of PALI- 2108, which is subject to a number of risks, including: • the continued enforceability of our research collaboration and license agreement with Giiant; • ~~the~~ **timely and** successful completion of **required clinical trials, which may be significantly slower** ~~our~~ **or costlier than we anticipate** ~~IND or CTA enabling studies and research; • the submission and approval of an~~ **and** ~~IND /~~ or ~~CTA~~ **produces results that do not achieve the primary or secondary endpoints of the trial (s)** ; • our ability to develop and implement clinical trial designs and protocols; • the successful initiation and completion of our **current** planned ~~pre- clinical studies and~~ clinical trials **and any additionally required preclinical studies, if any** ; • **our ability to retain third- party CROs on terms acceptable to us for the conduct and oversight of our anticipated clinical trials, including our Phase 1 clinical trial for PALI- 2108; • our ability to fund the development costs related to PALI- 2108' s clinical development; •** the approval by ~~the FDA~~ **Health Canada** or other regulatory ~~authority~~ **authorities** to commence the marketing of our product candidates; • the ability for us and third- parties, if applicable, to achieve and maintain compliance with our contractual obligations and applicable regulatory requirements; • the ability of our contract manufacturers to manufacture sufficient supply of our product candidates to meet the required ~~pre- clinical studies and~~ clinical trial supplies **and any additional required preclinical studies** ; • the ability of our 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 **regulations** ; • our ability to obtain favorable labeling for our product candidates through regulators that allows for successful commercialization; • acceptance by physicians, insurers, payors, and patients of the beneficial quality, safety and efficacy of our product candidates, if approved, including relative to alternative and competing treatments; • our ability to price our product candidates to recover our development costs and applicable milestone or royalty payments, and generate a satisfactory profit margin; and • our ability and our applicable collaboration and licensing partners' ability to establish and enforce intellectual property rights related to our product candidates and technologies. If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize our proposed product ~~candidate~~ **candidates . For example, we are currently enrolling and dosing subjects in our initial Phase 1 clinical trial of PALI- 2108 in Canada. We may experience delays or difficulties in finding suitable trial subjects, or in completing enrollment** . Such delays may result in increased costs and the failure to complete ~~any required regulatory activity~~ **the Phase 1 clinical trial of PALI- 2108 in Canada in a timely manner** . Even if **successfully completed, we must complete a number of additional clinical trials prior to obtaining** regulatory ~~approvals~~ **approval** ~~are obtained, we may never be able~~ to ~~successfully~~ commercialize our product candidates. Accordingly, we cannot make assurances that we will ever be able to generate sufficient revenue through the sale of any product candidates, if approved, to internally fund our business. There are substantial risks ~~inherent~~ in drug development, and, as a result, we may not be able to successfully develop **any product candidate. including our lead product candidate,** PALI- 2108. **We have initiated** ~~Our research and development efforts are focused on~~ a **Phase 1 clinical trial** ~~therapeutic based on PDE4 inhibitors. Our development~~ of PALI- 2108 ~~is in the early stages. However, such technology' s commercial feasibility and acceptance~~ in our target indication of **IBD** ~~inflammatory bowel disease are unknown~~ . **Drug** ~~Scientific research and~~ development requires **a** significant ~~amounts~~ **amount** of capital and **can** ~~takes~~ **take** a long time to reach commercial viability, if it can be achieved at all. During the ~~research and~~ development process, we may experience technological barriers that we may be unable to overcome. Further, certain underlying premises in our development programs have not been proven. Because of these and similar uncertainties, it is possible that our product candidates will not reach commercialization. If we are unable to successfully develop and commercialize our product candidates, **including our lead product candidate, PALI- 2108,** we will be unable to generate revenue 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 these rights or the failure to comply with **our** obligations under ~~this~~ **the license** agreement could materially harm our business and prevent us from developing or commercializing PALI- 2108, our lead product candidate. We are a party to **the** ~~a license agreement with~~ Giiant **License Agreement** under which we have been granted rights to patents and patent applications that are important to our business. We rely on this license agreement to be able to use various proprietary technologies that are

material to our business, including **patents,** ~~certain trade secrets~~ and patent applications that cover PALI- 2108. Our rights to **PALI- 2108** ~~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~~ **the Giiant** ~~license~~ **License** ~~agreement~~ **Agreement** . If we fail to comply with any of our obligations under the ~~license agreement with~~ Giiant **License Agreement** , Giiant may have the right to terminate the **Giiant** ~~license~~ **License** agreement, in which event we would not be able to continue the development **or our proposed commercialization** of PALI- 2108. Additionally, disputes may arise under the **Giiant** ~~license~~ **License** ~~agreement~~ **Agreement** regarding the intellectual property that is subject to such ~~license~~ agreement. If disputes over intellectual property that we have licensed, or in the future may license, prevent or impair our ability to maintain any of our license agreements **, including the Giiant License Agreement,** on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and technologies. ~~Pre- clinical~~ **Clinical** ~~and clinical~~ drug development is ~~very~~ expensive, time- consuming and uncertain. The ~~pre- clinical and~~ clinical development 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 **generate sufficient revenue to** cover their costs of development. In addition, we, any partner with which we may ~~in the future~~ collaborate, ~~the FDA~~ **Health Canada** , ~~or other~~ **any similar** regulatory ~~authorities~~ **authority** , ~~including~~ state and local agencies ~~and~~ **,** counterpart agencies in foreign countries, or **the applicable** ~~institutional~~ **Institutional** ~~review~~ **Review** ~~boards~~ **Board** (~~“~~ **"** IRB ~~”~~ **"**) at our trial sites, may suspend, delay, require modifications to or terminate our clinical trials, once begun, at any time **. We are currently conducting a Phase 1 clinical trial of PALI- 2108 in Canada, and the FDA or applicable foreign regulatory authorities may not accept data from such trials, or any other trial we conduct outside of the U. S. We have commenced a Phase 1 clinical trial for ulcerative colitis in Canada. However, we have not received approval from the FDA to commence any clinical trials in the U. S., and there is no guarantee that we will be able to obtain such approval in a timely manner, if at all. If our Phase 1 clinical trial is successful and we seek to initiate a Phase 2 clinical trial in the U. S, there is no certainty that the FDA will accept the data generated from our Canadian trial. The FDA' s acceptance of foreign clinical data is subject to certain conditions, including whether the trial was conducted in accordance with good clinical practices (“ GCP ”) and whether the FDA can validate the trial data through on- site inspections or other means. Moreover, the FDA will assess whether the trial design, patient population, endpoints, and other factors meet the standards expected for clinical trials conducted within the U. S. In addition, regulatory approval for clinical trials and eventual drug approval in the U. S. is a complex process, influenced by several factors, including: • the adequacy and relevance of the Phase 1 trial data in supporting progression to Phase 2, as evaluated by the FDA; • the ability of the trial to meet safety, efficacy, and other scientific requirements set by the FDA, which may differ from those of Health Canada; • whether the foreign clinical trial was conducted under an FDA- recognized regulatory authority, and whether FDA oversight is possible through monitoring or inspection of clinical sites; and • the FDA' s consideration of the risk- benefit ratio for continuing clinical development in the U. S., particularly based on data from a non- U. S. population. Furthermore, while the FDA does have the ability to approve drugs that have undergone clinical trials in foreign jurisdictions, including Canada, approval is generally contingent on demonstrating that the trial data align with FDA standards and regulatory expectations. It is also possible that we may be required to conduct additional trials in the U. S. to address any concerns regarding the applicability of the foreign trial data to the U. S. population or regulatory environment. There can be no assurance that we will successfully obtain FDA approval to initiate a Phase 1 clinical trial in the U. S. or that if our Canadian trial is successful, a subsequent Phase 2 trial. We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates. We are currently enrolling subjects in the Phase 1 clinical trial of PALI- 2108 in Canada. Identifying and qualifying subjects to participate in our current and anticipated future clinical trials is critical to our success. Our inability to enroll patients in our clinical trials on a timely basis could result in the trials being delayed or never completed. 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 patients' consents; • risk that enrolled patients will drop out before completion of the clinical trial; • patient referral practices of physicians; and, • ability to monitor patients adequately during and after treatment. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects. There can be no assurances that we will be able to complete enrollment for our anticipated Phase 1 clinical trial for PALI- 2108, and if we fail to do so, we may not be able to complete the trial on a timely basis, or at all** . We expect that our operations and development of PALI- 2108 will require substantially more capital than we currently have, and we cannot guarantee when or if we will be able to secure such additional funding. We have historically funded our operations and prior development efforts through the sale of our securities. Based on our existing cash resources and our current **business** ~~or future~~ plan ~~of operations~~ , we do not have adequate capital to fund our anticipated operations through the completion of the development of PALI- 2108. As a result, we ~~may~~ **will** need to secure additional funding. If we are not able to obtain ~~financing~~ **additional capital** in the future or on acceptable terms, we may ~~have~~ **need** to curtail our **anticipated clinical trials** ~~research and development efforts~~ as well as our operations **. Our product candidates, including our lead product candidate, PALI- 2108, may cause undesirable side effects or have other unexpected properties 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 PALI- 2108 could arise either during**

clinical development or, if approved, after it has been marketed. Undesirable side effects could cause us, any partners with which we 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 Health Canada, or comparable regulatory authorities like the FDA. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and Health Canada or comparable regulatory authorities, like the FDA, could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may have an adverse material effect on our business, financial condition, operating results and prospects. Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by a product after obtaining regulatory approval, a number of potentially negative consequences could result, which could prevent us or our potential partners from achieving or maintaining market acceptance of the product and could substantially increase the costs of commercializing such product . 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~~ **preclinical** 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~~ **preclinical** 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 **, possibly additional preclinical studies,** and the investment of significant funds to gain regulatory approval before it can be commercialized. **Although we commenced a Phase 1 clinical trial in Canada, there can be no assurances that gaining regulatory approval in Canada will result in regulatory approval from any other regulatory agency, including the FDA of the U. S.** The results of our ~~research and~~ human clinical testing of PALI- 2108 may not meet **applicable** regulatory requirements. If approved **in a jurisdiction** , 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 or receive applicable regulatory approvals. **On June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act " must exercise their independent judgment " and " may not defer to an agency interpretation of the law simply because a statute is ambiguous. " The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.** If we fail to obtain regulatory approvals, ~~it will~~ **or if there are significant changes in regulatory policies that result in increased litigation and judicial scrutiny leading to unexpected delays and increased cost, we may** not be able to market PALI- 2108 and our operations ~~may~~ **will** be adversely affected. If ~~pre- clinical and~~ clinical studies of PALI- 2108 do not yield successful results, **we may discontinue** ~~then~~ **the** ~~we may not continue to develop~~ **development of** 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~~ **preclinical** studies **that we have completed** ~~may be inconclusive, or they~~ may not be indicative of results that will be obtained in human clinical trials; • safety and efficacy results attained in ~~early human clinical~~ **preclinical studies** ~~trials, if approved,~~ may not be indicative of results that are obtained in ~~later~~ **our** clinical trials; • after reviewing ~~test~~ **early clinical trial** results, we may abandon projects that ~~it~~ **we** 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 **CROs,** 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~~ **Even if we were to** commence ~~or~~ **and** complete ~~pre- clinical studies or~~ **our** clinical trials involving PALI- 2108 as currently contemplated ~~or~~ **, they** 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 other first- line therapy). Similarly, it is possible that only a specific sub- set of patients safely responds to PALI- 2108. As a result, even if successful in 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 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 suspension or withdrawal, closure of a facility or substantial fines. If regulatory approval to ~~sell~~ **market and commercialize** PALI- 2108 is received, regulatory agencies will subject PALI- 2108, as well as the manufacturing facilities, to continual review and periodic inspection. If previously unknown problems with a product or manufacturing and laboratory facility are discovered, or we fail to comply with applicable regulatory approval requirements, a regulatory agency may impose restrictions on PALI- 2108 or us. The agency may require the withdrawal of PALI- 2108 from the market, closure of the facility or substantial fines . We may in the future conduct..... 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 **in the applicable jurisdiction** , including **, for example,** Medicare and Medicaid **in the U. S.** , 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, both the federal and state governments in the ~~United States~~ **U. S.** and foreign governments continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations. If future reimbursement for PALI- 2108, subject to approval, ~~are~~ **is** 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~~ **we** may incur substantial liability for a product candidate and **we** may ~~have~~ **need** to limit 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 clinical trial participants, consumers, health- care providers, pharmaceutical companies, or others selling our products. If we cannot successfully defend ourselves against these claims, ~~it~~ **we** may incur substantial liabilities. Regardless of merit or eventual outcomes of such claims, product liability claims may result 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 other claimants; and • loss of revenues. Our insurance coverage may not be sufficient to reimburse ~~it~~ **us** for all expenses or losses ~~it~~ **we** may suffer. Moreover, insurance coverage is becoming increasingly expensive **,** and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect ~~it~~ **us** against losses. 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 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 that are contained in the final ~~FDA-~~ approved labeling ~~, or other~~ **; • any requirement of an** 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 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 any of our product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit 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 to shorten the 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 on our ability to manage such relationship, and to a certain extent, to the efforts of Giiant, which are beyond our control.~~ Risks Related to ~~our~~ **Our** Business We have a limited operating history and have never generated any revenues from product sales. We are a biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. ~~We~~ **While we** were initially formed in 2001 ~~and~~ **,** our operations, to date, have been limited to business planning, raising capital and other research and development activities related to our product candidates. We **additionally adopted a new business plan in September 2023 upon entering into the Giiant License Agreement. Since that time, we** have not yet demonstrated an ability to successfully complete any clinical trials and ~~has~~ **have** never completed the development of any product candidate, nor ~~has it~~ **have we** ever generated any revenue from product sales ~~or otherwise~~ . Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if ~~it~~ **we** 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 **clinical** 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~~ **. We commenced our initial Phase 1 clinical trial** of ~~development~~ **PALI- 2108 in November of 2024** . Thus, we have limited experience and have not yet demonstrated ~~our~~ **an** 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 **from Health Canada** and **/ or** approval from similar foreign regulatory bodies **, such as the FDA; • Retain qualified CROs to oversee and manage our Phase 1 clinical trial for PALI- 2108 and future clinical trials** ; • 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~~ **preclinical** 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 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 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. If at any time during this period the closing bid price of our common stock is at least $ 1. 00 for a minimum of 10 consecutive business days, we will regain compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for listing on The Nasdaq Capital Market absent noncompliance with any other requirement for continued listing. 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 with the exception of bid price, and we provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a 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 then 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 requirements for continued listing of our shares on the Nasdaq Capital Market in the future or that it will comply with the other continued listing requirements. Notwithstanding, we 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 to a number of negative implications, including an adverse effect on the price of our common stock, 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. 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 assurance that our common stock would be eligible for trading on any such alternative exchange or markets. Moreover, if our common stock is delisted, it may come within the definition of " penny stock " under the Exchange Act, which imposes additional sales practice requirements on broker- dealers who sell securities to persons other than established customers and accredited investors. For example, we and / or broker- dealers are required to make a special suitability determination for purchases of such securities and must receive a purchaser' s 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 the securities and, if the broker- dealer is the sole market- maker for the 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 may reduce trading activity in the secondary market for our common stock and may impact the ability or willingness of 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 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 another stock market. In order to maintain this listing, we must satisfy certain continued listing standards, including but not limited to the 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 next annual shareholders' meeting or March 4, 2025, or (ii) 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 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 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, technical and managerial personnel. We do not maintain key person life insurance for any of our executives ~~and we do not maintain employment agreements with many senior employees~~ . Competition for qualified employees in the pharmaceutical industry is high, and our ability to execute our strategy will depend in part on our ability to continue to attract and retain qualified scientists and management. If we are unable to find, hire **,** and retain qualified individuals, ~~it will have difficulty implementing~~ **we may be unable to execute** our business plan in a timely manner, ~~or~~ **if** at all. We may choose to discontinue ~~developing~~ **development** or ~~commercializing~~ **commercialization** any of our product candidates, or may choose ~~to~~ not **to** commercialize product candidates 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 **(s)** or changes in or failure to comply with applicable regulatory requirements. If we temporarily pause or terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses, which could have an adverse effect on us and our business. Our inability to successfully in- license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business. 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 internal research and development capabilities are limited, ~~it~~ **we** may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to ~~it~~ **us** . The success of this strategy depends partly on our ability to identify and select promising pharmaceutical product candidates and **approved** 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 for the license or acquisition of product candidates and approved products. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional **approved products or** product candidates on terms that ~~it~~ **we** ~~finds~~ **find** acceptable **,** or at all. Further, any product candidate that we acquire or ~~licenses~~ **license** may require additional development efforts prior to commercial sale, including ~~pre- clinical~~ **preclinical** 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 cannot provide assurance that any approved products that ~~it~~ **we** ~~acquires~~ **acquire** will be manufactured or sold profitably or achieve market acceptance. **Changes in funding for the FDA and,** ~~We may seek to avail ourselves of mechanisms to expedite the~~ **other government agencies or**

comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent these agencies or authorities from performing normal business functions on which the operations of our business may rely, which could negatively impact our business. The ability of the FDA or comparable foreign regulatory authorities to review and approve new products, to provide feedback on clinical trials and development **programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key leadership and other personnel, the sufficiency of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies or comparable foreign regulatory authorities on which** ~~or~~ **our** ~~approval~~ **operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other, other government agencies or comparable foreign regulatory authorities may also slow the time necessary** for ~~product candidates it may pursue in~~ **new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over** the ~~future~~ **last several years, the U. S. government has shut down several times and certain regulatory agencies** , such as **the FDA** ~~Fast Track or breakthrough designation~~ , **have had** ~~but such mechanisms may not actually lead~~ to **furlough critical employees and stop critical activities. If** a ~~faster development~~ **prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process** ~~or~~ **our** regulatory **submissions** ~~review or approval process. We may seek to avail ourselves of Fast Track designation~~ , **which could have** ~~breakthrough designation, or priority review for product candidates it may pursue in the future. For example, if~~ a **material adverse effect on** ~~drug is intended for the treatment of a serious or~~ **our business** ~~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 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 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 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 clinical development program~~ . Risks Related to ~~our~~ **Our** Dependence on Third Parties **.We may in the future conduct clinical trials for PALI- 2108 outside the United States,and the FDA or applicable foreign regulatory authorities may not accept data from such trials.We may in the future choose to conduct 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 business plan.** We anticipate relying on third- party CROs and other third parties to conduct and oversee our **pre- clinical studies and** clinical trials.If these third parties do not meet our requirements or otherwise conduct the **studies or** trials as required,we may not be able to satisfy our contractual obligations ~~for~~ - **or** obtain regulatory approval for,or commercialize **,** our product candidates.We **may** ~~have retained a CRO to oversee our Phase 1 clinical trial for PALI- 2108 in Canada.We are likely to~~ rely on third- party CROs to conduct and oversee our ~~other~~ anticipated **pre- clinical studies and** clinical trials and other aspects of product development.We also expect to rely on various medical institutions,clinical investigators and contract laboratories to conduct our trials in accordance with our 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 expect to rely heavily on these parties for the execution of our clinical trials and **pre-** ~~any additionally required preclinical~~ --- **clinical** studies and will control only certain aspects of their activities.We and our CROs and other third- party contractors will be required to comply with GCP and **good laboratory practice (“** GLP ~~regulations~~ **”) requirements** ,which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities ~~,such as Health Canada,with respect to our Phase 1 clinical trial for PALI- 2108~~ .Regulatory authorities enforce these GCP ~~or~~ **and** GLP ~~regulations~~ **requirements** through periodic inspections of trial sponsors,principal investigators and trial sites.If we or any of these third parties fail to comply with applicable GCP and GLP ~~regulations~~ **requirements** ,or reveal noncompliance from an audit or inspection,any clinical data generated in our clinical trials may be deemed unreliable ~~,~~ and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications.We cannot assure that upon inspection by a given regulatory authority **,**

such regulatory authority will determine whether **or not** any of our **clinical or pre-** clinical trials comply with applicable GCP ~~or~~ **and** GLP ~~regulations~~ **requirements** .In addition,our clinical trials generally must be conducted with compounds produced under cGMP regulations.Our failure to comply with these regulations and policies may require ~~us~~ **it** to repeat clinical trials,which would be costly and delay the regulatory approval process. **If** ~~In the event that we are unable to retain a qualified CRO for our Phase 1 clinical trial for PALI- 2108,or~~ any ~~other anticipated clinical trial,it would delay planned clinical operations and result in additional cost and expense.Additionally,if our current CRO for our Phase 1 clinical trial in Canada or if any~~ of our CROs ~~that we retain in the future~~ were to terminate their involvement with us,there is no assurance that we would be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms ~~.We depend on two qualified suppliers for the active pharmaceutical ingredient used in the clinical trials of PALI- 2108.Insufficient availability of the API or other raw materials necessary to manufacture PALI- 2108,or the inability of our suppliers to manufacture and supply our products on commercially reasonable terms,could adversely impact our business,results of operations and financial condition.We have two qualified suppliers for the API used in PALI- 2108.We do not have,and we do not intend to establish in the foreseeable future,internal manufacturing capabilities.Instead,we intend to use the facilities of third- party manufacturers to produce the materials used in our clinical trials.Our dependence on third parties for the supply and manufacture of PALI- 2108 and any future product candidates may adversely affect our ability to obtain our products in a timely or competitive manner,if at all.Any supply shortages,quality concerns,or failure to obtain sufficient API,excipients,or components from our suppliers,including disruptions caused by,among other things,supply chain delays,public health emergencies,climate events,or political unrest would adversely affect our business,results of operations and financial condition.In particular,our suppliers may be impacted by epidemics,pandemics or other disease outbreaks or public health emergencies and~~ We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates. We **currently rely on and** expect **to continue** to rely upon the efforts of third parties for the successful development and commercialization of our product candidates. The clinical and commercial success of our 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 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 our product candidates; and • other risks in potentially meeting our product commercialization schedule or satisfying the requirements of our end- users. We cannot provide any assurance that we will be able to establish or maintain third- party relationships in order to successfully develop and commercialize our product candidates. We **currently rely** ~~anticipate relying completely~~ on third- party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates. We do not currently have, nor do we **currently** plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute ~~pre- clinical,~~ clinical or commercial quantities of drug substances or products. **Although** ~~Additionally,~~ we have ~~not~~ entered into a ~~long- term~~ commercial supply agreement to provide us with such drug substances or products **for** ~~. As a result,~~ our **current Phase 1 clinical trial, our future** ability to develop and commercialize, if approved, our product candidates is dependent on our ability to obtain the APIs and other substances and materials used in 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- clinical~~ **preclinical** and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, we may be unable to continue to develop or commercialize our products and product candidates, which could adversely affect us and our business. We are dependent on our contract suppliers and manufacturers for day- to- day compliance with applicable laws and cGMP **regulations** for production of our proposed 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 may not be able to commercialize or obtain regulatory approval for the affected product or product candidates successfully, and we may be held liable ~~for injuries sustained~~ as a result. We expect to continue to depend on third- party contract suppliers and manufacturers. Our supply and manufacturing agreements do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. Additionally, any damage to or destruction of our third- party manufacturers' or suppliers' facilities or equipment, even by force majeure, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, may misappropriate our trade secrets or other proprietary information. **Furthermore** ~~In addition~~ , the manufacturing facilities of ~~certain of~~ our suppliers **are** ~~may be~~ located outside of the ~~United States~~ **U. S** . This may give rise to difficulties in importing our products or product candidates or their components into the ~~United States~~ **U. S.** or other countries **. We currently have agreements in place with foreign third parties in China and other countries to provide the necessary clinical supply of our API. Termination of or limitations on our relationships with foreign third parties that manufacture the API used in PALI- 2108 may arise if U. S. legislation, tariffs, sanctions, trade restrictions, or other U. S. and foreign regulatory requirements, or prohibitions restrict our ability to engage with these foreign third parties. Further, any such actions could adversely impact our current and future arrangements with our foreign suppliers, including our current Chinese drug manufacturer, which could increase the cost or reduce the supply of material available to us or delay the procurement or supply of such material used in our clinical trial** . Risks Related to Our Financial Operations We have expressed substantial doubt about our ability to continue as a going concern. Management has determined that there is substantial doubt about our ability to continue as a going concern for a period of one year following the issuance of this **Annual** ~~report~~ **Report on Form 10- K** . This determination was based on conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the **consolidated** financial statements are issued, including ~~: (i) the 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 ~~to~~ **, which is** not ~~be~~ sufficient to fund our anticipated level of operations for the next 12 months ~~; and (ii) the uncertainties of the cost and timing of our efforts to in- license or acquire a new product candidate~~ . Our future consolidated financial statements may include a similar qualification about our ability to continue as a going concern. Our year- end and interim consolidated financial statements were prepared assuming that ~~it~~ **we** will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us 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 $ **14. 4 million and $** 12 ~~. 3 million and $ 14~~ . 3 million for the years ended December 31, ~~2023~~ **2024** and December 31, ~~2022~~ **2023** , respectively. We expect that our operating losses will continue for the foreseeable future as ~~it~~ **we** ~~continues~~ **continue** 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~~ **we** may not be able to realize revenues at a level that would allow ~~it~~ **us** to achieve or sustain profitability. Accordingly, we may never generate significant revenue and, even if **we** ~~it does~~ generate significant revenue, ~~it~~ **we** may never achieve profitability. Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in our consolidated financial statements. Our management has identified a material weakness in 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. If our remaining material weakness, which management concluded is still present as of the date of these financial statements, is not remediated, or if we identify further material weaknesses in our internal controls, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our consolidated financial statements and a failure to meet our reporting and financial obligations. ~~Changing circumstances and market conditions, some of which may be beyond our 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 control, could impair our ability to access 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 not have any funds at SVB, if other banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, we may be unable to access, and we may lose, some or all of 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 might not be able to timely pay key vendors and others. We regularly maintain cash balances that are not insured or are in excess of the FDIC' s insurance limit. Any delay in our ability to access 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 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~~ **in certain countries** . The 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~~ **and** 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 **or the ability to obtain future patent protections** , which may have an adverse impact on our business, financial condition and operating results. Our ability to obtain, maintain and **/ or** enforce patents is uncertain and involves complex legal and factual questions **,** especially across **varying** 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 **make it** ~~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 **we** are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents ~~do~~ **are** successfully ~~issue~~ **issued**, 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 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 **assignment and** protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that ~~binding~~ **such** 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~~ **we** 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 **vary between** ~~differ in certain~~ countries, particularly developing ~~countries~~ **nations**. In addition, the laws of some ~~foreign~~ countries do not protect intellectual property rights to the same extent as **the** laws ~~in~~ **of all** ~~the~~ **other** ~~United States~~ **countries or jurisdictions**, especially when it comes to granting use and other ~~kinds~~ **types** 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~~ **using** our inventions **or** ~~in all countries outside the United States and~~ even in launching an identical version of our product ~~notwithstanding~~ **even if** we ~~have~~ **hold** a valid patent ~~in that country~~. Competitors may use our technologies in jurisdictions where we have not obtained patent protection, or **they may** produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement ~~on infringing~~ **against such** activities is inadequate or where we have no patents. These products ~~may~~ **could** compete with ~~our~~ **ours** ~~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 **applicable** ~~the U. S. Patent and Trade Office (" USPTO") and foreign~~ patent agencies **, which** ~~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. **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.** 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-~~ **The Giiant License Agreement pursuant to which we** license ~~agreement with respect to our lead product candidate,~~ PALI- 2108 ~~. This license agreement imposes various~~ **, and other assets of Giiant, contains certain requirements related to** diligence, milestone, royalty, insurance **, expense reimbursement,** and other obligations ~~on us~~. If we fail to comply with these obligations, **Giiant** ~~the licensor~~ may **have the ability to** terminate the license **, subject to certain requirements as more fully set forth in the Giiant License Agreement**. ~~The loss of such rights~~ **If the license granted thereunder were to be terminated, our business, financial condition, operating results, and prospects** would **be** materially adversely ~~affect~~ **affected** ~~our business, financial condition, operating results and prospects~~. We may be subject to patent infringement claims, which could result in substantial costs ~~,~~ **and** liabilities **,** and **could** 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, **regardless of** 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~~ **the related** litigation could be protracted, expensive, a distraction to our management team, **and** 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 have used and we intend to use the proceeds from our previous offerings and any future offerings, to, among other uses, advance PALI- 2108 through clinical development, advancing the remainder of the existing portfolio through preclinical studies and into INDs or their equivalent in foreign jurisdictions, our research and development activities and for general working capital needs** . 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~~ **preclinical** testing and clinical trials; the ability to manufacture sufficient drug supplies to complete ~~pre- clinical and~~ clinical trials **or any additional preclinical studies required** ; 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~~ **, which** could **inhibit our ability to achieve our business objectives. Given our limited cash reserves and the** ~~significantly~~ -- **significant** ~~dilute~~ **amount of capital that we will likely need to fund our operations and business plan, our** stockholders ~~'~~ **will likely experience significant dilution to their** 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~~ **need** 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, **the price of** our **common** 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~~ **our** 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 **, and employment agreements with our named executive officers** ; • 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 **, particularly in the micro- cap and nano- cap companies,** 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~~ **stockholders** 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. **Our common stock could be delisted from the Nasdaq Stock Market if**

we are unable to maintain compliance with the Nasdaq Stock Market' s continued listing standards. Our common stock is listed on the Nasdaq Stock Market. There are a number of continued listing requirements that we must satisfy in order to maintain our listing on The Nasdaq Stock Market, including the requirement to maintain a minimum bid price of at least $ 1. 00 (the " Bid Price Rule "). Although we are currently in compliance with the Bid Price Rule, we have been unable to comply with this rule in the past. For example, in October 2023, we were notified that we were no longer in compliance with the Bid Price Rule and had 180 days to cure such deficiency. On April 5, 2024, we effected a 1- for- 15 reverse stock split and we were notified by the Nasdaq Stock Market that as of April 19, 2024, we were back in compliance with the Bid Price Rule. Although we are in compliance with the Bid Price Rule as of the date of this Annual Report on Form 10- K, on March 17, 2025, our stock price began trading below $ 1. 00. Notwithstanding our current compliance with the Bid Price Rule, in the event that our common stock trades below $ 1. 00 for 30 consecutive business days, Nasdaq may notify us that we are no longer in compliance with the Bid Price Rule and may have 180 days to cure such deficiency. If we are unable to cure such deficiency, we may be subject to delisting. If we fail to comply with the Bid Price Rule in the future, or any of the other continued listing requirements, there can be no assurance that we will be able to regain compliance. The delisting of our common stock would likely adversely affect the market liquidity and market price of our common stock and our ability to obtain financing for the continuation of our operations and / or result in the loss of confidence by investors. 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~~ **2024** , the last business day of our most recently completed second fiscal quarter, our public float ~~is~~ **was** 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~~ **We do not anticipate paying any dividends in the foreseeable future. We** ~~current~~ **currently plan to** ~~expectation is that we will~~ retain our future earnings **, if any,** to fund the development and growth of our business. As a result, capital appreciation, if any, of our shares will **likely** be ~~your~~ **the** sole source of gain, if any, **for our stockholders** 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~~ **we do** 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~~ **downgrades** our stock or ~~issue~~ **issues** 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~~ **us** 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 **, as amended (" Certificate of Incorporation "),** and bylaws **, as amended (" 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~~ **Delaware General Corporation Law** , 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~~ **Certificate** of ~~incorporation~~ **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 **of such preferred stock** . As of December 31, ~~2023~~ **2024** , we had outstanding, common stock or securities convertible into common stock, totaling 9, ~~270~~ **567** , ~~894~~ **496** shares. As a result, we are authorized to issue up to an additional 270, ~~729~~ **432** , ~~106~~ **507** shares of common stock or common stock equivalents under our ~~certificate~~ **Certificate** of ~~incorporation~~ **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~~ **will** 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~~ **stockholders will likely** 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 **that** we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors ~~may~~ **will likely** be materially diluted by **the initial and** subsequent sales. **Additionally** ~~These sales may also result in material dilution to our existing shareholders~~ , ~~and~~ new investors ~~could~~ **may** gain rights superior to existing ~~shareholders~~ **stockholders, depending on the terms of such transactions and types of securities** . 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~~ **stockholders** to experience additional dilution, which could cause our stock price to fall. General Risk Factors Our business could be adversely affected by the effects of health pandemics or epidemics, such as 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 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 from 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' facilities, would negatively impact our trial activities. In addition, we rely on independent clinical investigators, CROs, and other 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, such as the COVID- 19 pandemic, may affect their ability to devote sufficient time and resources to our programs or to travel to sites 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 Russia- Ukraine and Israel- Hamas ~~conflict~~ **conflicts**). The financial institutions in which we hold our cash and cash equivalents are subject to risk of failure. For example, 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 may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn. 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, ~~it~~ **we** 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, our remote workforce poses increased risks to our information technology systems and data, as 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 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 operations, including material disruptions of 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~~ **parties** 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 ~~it relies~~ **we rely**) 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 sponsor clinical trials, any breach or disruption that compromises patient data and identities could generate significant reputational damage, which may affect trust in us 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 regulatory approval efforts and significantly increase 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 business and operations would suffer in the event of system failures, cyber- attacks or a deficiency in our cybersecurity. Despite the implementation of security measures, our internal computer systems, and those of 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 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 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 operations, it could result in a material disruption of our development programs and our business operations. In addition, since we 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 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 regulatory approval efforts and significantly increase 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 data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products and product candidates could be delayed.