Risk Factors Comparison 2024-12-13 to 2023-12-15 Form: 10-K

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Certain factors may have a material adverse effect on our business, prospects, financial condition and results of operations. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10- K, including our financial statements and the related notes, before deciding to invest in our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business and cause the market price of our securities to decline. In addition, many of the following risk factors could be exacerbated by any worsening of the global business and economic environment or the resurgence of Covid- 19 or other public health threats. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects could be materially and adversely affected. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward- looking statements. See " Forward- Looking Statements And Other Matters " for a discussion of some of the forward- looking statements that are qualified by these risk factors. Summary of Risks The following summarizes key risks and uncertainties that could materially adversely affect us. You should read this summary together with the more detailed description of each risk factor contained below. ● We are a late- stage biopharmaceutical company with no products approved for commercial sale, and we have incurred significant losses since our inception and expect to continue to incur losses and may never generate profits from operations or maintain profitability. ● We will need substantial additional funding to finance our operations through regulatory approval of one or more of our product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations. ● We depend heavily on the success of our drug product candidates. If we are unable to obtain regulatory approval or commercialize one or more of these experimental treatments, or experience significant delays in doing so, our business will be materially harmed. We cannot give any assurance that we will receive regulatory approval for such product candidates or any other product candidates, which is necessary before they can be commercialized. ● We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. ● A successful sPLA2, anti- TLR4 or anti- CXCL10 drug has not been developed to date and we can provide no assurances that we will be successful or that there will be no adverse side effects. ● Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. ● If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and any of our other current or future product candidates, we may not be successful in commercializing the applicable product candidate if it receives marketing approval. ● Even if we are able to commercialize one of our product candidates, the product may become subject to unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives, which would harm our business. ● We face substantial competition, which may result in others discovering, developing or commercializing products to treat our target indications or markets before or more successfully than we do. ● We will be dependent on third parties for manufacturing, including optimization, technology transfers and scaling up of clinical scale quantities of all of our product candidates. ● The manufacturing of our monoclonal antibody candidates is complex and subject to a multitude of risks. These manufacturing risks could substantially increase our costs and limit supply of these drug candidates for clinical development, and commercialization. ● We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials. ● Even if we complete the necessary clinical trials, the marketing approval process is expensive, time consuming and uncertain. If we are not able to obtain, or if there are delays in obtaining, required marketing approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired. ● Even if we obtain marketing approval for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue. ● If we are unable to obtain and maintain patent protection for our licensed technology and products, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our licensed technology and products may be adversely affected. ● The ownership of our common shares is highly concentrated, which may prevent you and other shareholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our common shares price to decline. **● If we fail to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common shares, the delisting could adversely affect the market liquidity of our common shares and the market price of our common shares could decrease and our ability to access the capital markets could be negatively impacted.** ~~24Risks~~ -- **Risks** Related to Our Business, Financial Position and Capital Requirements Since inception, we have incurred significant operating losses. At September 30, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~52~~ **58** . ~~4~~ **6** million. We have historically financed operations primarily through issuances of common shares, the exercise of common share purchase warrants, convertible preferred shares, convertible loans, government grants and tax incentives. We have devoted substantially all of our efforts to research and development, including clinical trials, and have not completed the development of any of our drug candidates. We expect to continue to incur significant expenses and operating losses without corresponding revenue for the foreseeable future as we

continue the development of, and seek marketing approvals for our product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company in the U. S. and Canada. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. Based on our current plans, we do not expect to generate significant revenue unless and until we or a current or potential future licensee obtains marketing approval for, and commercializes, one or more of our product candidates, which may require several years. Neither we nor a licensee may ever succeed in obtaining marketing approval for, or commercializing our product candidates and, even if marketing approval is obtained, we may never generate revenues that are significant enough to generate profits from operations. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our securities and our ability to raise capital **. Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern. We have recognized recurring losses, and at September 30, 2024, we had an accumulated deficit of $ 58. 6 million. We anticipate operating losses to continue for the foreseeable future due to, among other things expenses related to ongoing activities to research, develop and commercialize our product candidates. We expect that our cash and cash equivalents at September 30, 2024, together with the proceeds from the sale of Preferred Shares (as defined below) to PN MPC (as defined below), net proceeds from the HCW ATM (as defined below) and reimbursement of eligibility R & D expenses under the 2023 SIF Agreement, will not be sufficient to fund our operating and capital requirements at least 12 months from the filing of this Form 10- K. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative and research and development activities are forward- looking statements and involve risks and uncertainties. The financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials. These factors among others create a substantial doubt about our ability to continue as a going concern** . We expect our research and development expenses to increase substantially in the future, particularly for any drug candidates beyond Phase 2 clinical development or if we expand the number of drug candidates in clinical studies. In addition, if we obtain marketing approval for any of our product candidates that are not then subject to licensing, collaboration or similar arrangements with third parties, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We cannot be certain that additional funding will be available on acceptable terms, or at all. In addition, future debt financing into which we may enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our shares, make certain investments and engage in certain merger, consolidation or asset sale transactions. **In addition, any debt financing would require us to dedicate a portion of our cash resources to the payment of interest and principal, thereby reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes.** If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, share price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited. ~~25Raising~~ -- **Raising** additional capital may cause dilution to our investors, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, licensing, collaboration or similar arrangements, grants and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common shares. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our existing shareholders. If we raise additional funds through licensing, collaboration or similar arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research and development programs or product candidates or to grant licenses on terms that may not be favorable to us. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development of our product candidates. To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, clinical trials of our product candidates, and other operations and potential product acquisitions and in- licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in- licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for

general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, in- licensing or similar strategic business transaction. We partially rely on government grants to contribute to our EB05 (paridiprubart) development program. If we are unable to satisfy our contractual obligations and manage our covenants or meet expected **milestones** ~~under both SIF agreements~~ , the development of EB05 may be extended, delayed, modified, or terminated and we may be required to repay all or part of the grant earlier than expected. In February 2021, we and Edesa Biotech Research signed the 2021 SIF Agreement whereby the Government of Canada agreed to contribute C $ 14. 1 million in nonrepayable funding for an international Phase 2 study and certain pre- clinical experiments. In the event that we or Edesa Biotech Research breach our obligations under the 2021 SIF Agreement, subject to applicable cure, the SIF may exercise a number of remedies, including demanding repayment of funding previously received and / or terminating the agreement. The performance obligations of Edesa Biotech Research under the contribution agreement are guaranteed by us. All potential funding available under the 2021 SIF Agreement has been received. As of the date of this filing, we have met all of our performance and reporting requirements under the 2021 SIF Agreement. On October 12, 2023, we and Edesa Biotech Research signed the 2023 SIF Agreement whereby the Government of Canada agreed to contribute up to C $ 23 million from the SIF in partially repayable funding toward of the development and commercialization of our investigational therapy EB05. Under the 2023 SIF Agreement, we agreed to complete the project, to be conducted exclusively in Canada except as permitted otherwise under certain circumstances, on or before December 31, 2025. We also have agreed to certain financial and non- financial covenants and other obligations in relation to EB05, including the achievement of certain headcount requirements in Canada, the maintenance of a collaboration with a Canadian research institute or post- secondary institutions, and the maintenance of certain research and development expenditures in Canada. In an event of default, such as our breach of our covenants and obligations under either the 2023 SIF Agreement or the 2021 SIF Agreement, the Government of Canada may suspend or terminate its contribution to the project, or require repayment. As a result, if we default on our obligations under the SIF agreements, we may not have sufficient funds available to continue the Phase 3 clinical study of our investigational therapy EB05, and we cannot be certain that we will be able to obtain additional capital to fund the program. We are currently not in default of our obligations per the terms of either SIF agreement. **In June 2024, EB05 was selected through a competitive process by the Biomedical Advanced Research and Development Authority (BARDA), as one of three drug candidates for evaluation in a U. S. government- funded Phase 2 platform study. The randomized, double- blinded, placebo- controlled, multi- center clinical trial is investigating novel threat- agnostic host- directed therapeutics, including EB05, in hospitalized adult patients with ARDS due to a variety of causes. We are providing drug products to the study as well as technical support at our own expense. Given the BARDA- sponsored study opportunity, we have shifted our clinical focus for EB05 to general ARDS from Covid- 19 induced ARDS.** ~~26Our -~~ **Our** ~~existing~~ **plan is to await the results of the BARDA- funded study before continuing with our Canadian government- supported Phase 3 study, which had exclusively recruited ARDS patients hospitalized with Covid- 19. As a result, we have discontinued enrollment in a Covid- 19 focused Phase 3 study** and **plan to file a new study design with FDA and Health Canada based on the results of the BARDA- funded ARDS study. We believe this strategy provides a more efficient and cost- effective path toward a commercially approved therapy for general ARDS, increases the potential commercial opportunity for EB05 and better aligns our development programs with government goals for HDTs as well as interest from potential strategic commercialization and licensing partners. Any changes we have made and make in the future to our clinical plans and enrollment criteria may limit how data from previously enrolled subjects are utilized by the company for regulatory purposes. Any failures on our part to satisfy** any ~~future indebtedness~~ **of our obligations under the above agreements** could adversely affect ~~our -~~ **or terminate** ~~ability to operate~~ our ~~business. In October 2023, we entered into a credit agreement with Pardeep Nijhawan Medicine Professional Corporation, an entity controlled by Dr. Nijhawan, our Chief Executive Officer, Secretary and member of our board of directors, providing for an unsecured revolving credit facility in the principal amount of up to $ 10 million. Such credit facility combined with our other financial obligations and contractual commitments, including any future indebtedness, could have adverse consequences, including: · requiring us to dedicate a portion of our cash resources to the payment of interest and principal, thereby reducing money available to fund working capital, capital expenditures, product~~ development **of EB05** ~~and other general corporate purposes; · increasing our vulnerability to adverse changes in general economic, industry and market conditions; · subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing; and · limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete~~ . We have not completed development of and / or obtained regulatory approval for any of our product candidates. Development will require the commitment of substantial financial resources, extensive product candidate development, and clinical trials. This process takes years of effort without any assurance of ultimate success. Our ability to generate product revenues, which may not occur for multiple years, if at all, will depend heavily on the successful development and commercialization of our drug product candidates. The success of our product candidates will depend on a number of factors, including, but not limited to: ~~-~~● our ability to obtain additional capital from potential future licensing, collaboration or similar arrangements or from any future offering of our debt or equity securities; ~~-~~● our ability to identify and enter into potential future licenses or other collaboration arrangements with third parties and the terms of the arrangements; ~~-~~● our timing to obtain applicable regulatory approvals; ~~-~~● successful completion of clinical development; ~~-~~● the ability to provide acceptable evidence demonstrating a product candidates' safety and efficacy; ~~-~~● receipt of marketing approvals from applicable regulatory authorities and similar foreign regulatory authorities; ~~-~~● the availability of raw materials to produce our product candidates; ~~-~~● obtaining and maintaining commercial manufacturing arrangements with third- party manufacturers or establishing commercial- scale manufacturing capabilities; ~~-~~● obtaining and maintaining patent and trade secret protection and regulatory exclusivity; ~~-~~● establishing sales, marketing and distribution capabilities; ~~-~~●

generating commercial sales of the product candidate, if and when approved, whether alone or in collaboration with others; ● acceptance of the product candidate, if and when approved, by patients, the medical community and third- party payors; ● effectively competing with other therapies; and ● maintaining an acceptable safety profile of the product candidate following approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any of our product candidates, which would materially harm our business. Many of these factors are beyond our control. Accordingly, we may never be able to generate revenues through the license or sale of any of our product candidates. ~~27Our~~ -- **Our** product development efforts with respect to our product candidates may fail for many reasons, including but not limited to: ● the failure of the product candidate in clinical studies; ● adverse patient reactions to the product candidate or indications of other safety concerns; ● insufficient clinical trial data to support the effectiveness or superiority of the product candidate; ● the inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost- efficient manner; and ● changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive. Deterioration in general economic conditions in the U. S., Canada and globally, including the effect of prolonged periods of inflation on our suppliers, third- party service providers and potential partners, could harm our business and results of operations. Our business and results of operations could be adversely affected by changes in national or global economic conditions. These conditions include but are not limited to inflation, rising interest rates, availability of capital markets, energy availability and costs, the negative impacts caused by pandemics and public health crises, negative impacts resulting from the military conflict between Russia and the Ukraine, and the effects of governmental initiatives to manage economic conditions. Impacts of such conditions could be passed on to our business in the form of higher costs for labor and materials, higher investigator fees, possible reductions in pharmaceutical industry- wide spending on research and development and acquisitions and higher costs of capital. Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. Our primarily operating entity, Edesa Biotech Research, Inc., was formed in July 2015. To date, our operations have been limited to organization and staffing, developing and securing our technology, entering into licensing arrangements, raising capital and undertaking preclinical studies and clinical trials of our product candidates. We have not yet demonstrated our ability to successfully complete development of any product candidate, obtain marketing approval, manufacture a commercial- scale product, or arrange for a third- party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Assuming we obtain marketing approval for any of our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history. We are exposed to risks related to currency exchange rates. We conduct a significant portion of our operations outside of the U. S. Because our financial statements are presented in U. S. dollars, changes in currency exchange rates have had and could have in the future a significant effect on our operating results when our operating results are translated into U. S. dollars. We are subject to anti- corruption laws, as well as export control laws, customs laws, sanctions laws, privacy laws and other laws governing our operations. If we fail to comply with these laws, it could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition. Our operations are subject to anti- corruption laws, including the U. S. Foreign Corrupt Practices Act (FCPA), and other anti- corruption laws that apply in countries where we do business and may do business in the future. We are also subject to other laws and regulations governing our international operations, including regulations administered by the government of the U. S. and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti- corruption laws. If we are not in compliance, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Similarly, compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and our failure to comply with data protection laws and regulations could lead to government enforcement actions, which would cause our business and reputation to suffer. ~~28If~~ **If** we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations produce hazardous waste products. We expect to contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could cause significant liability for us and harm our reputation. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and collaborators, including intentional failures to comply

with FDA or Office of Inspector General regulations or similar regulations of comparable non- U. S. regulatory authorities, provide accurate information to the FDA or comparable non- U. S. regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non- U. S. regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Such actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse impact on our business, financial condition, results of operations and prospects including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, loss of eligibility to obtain marketing approvals from the FDA, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements if subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with any of these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our operating results. We expect to expand our capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. We expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, finance and administration and, potentially, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. If we are not able to effectively manage our growth and expand our organization, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals. ~~29Our~~ -- **Our** future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on Dr. Pardeep Nijhawan, our CEO and Secretary; and Michael Brooks, our President; as well as other principal members of our management and scientific teams. Although we have employment agreements with each of our executives, these agreements do not prevent our executives from terminating their employment at any time. The unplanned loss of the services of any of these persons could materially impact the achievement of our research, development, financial and commercialization objectives. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. Recruiting and retaining qualified personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies for similar personnel. We could have difficulty attracting experienced personnel to our Company and may be required to expend significant financial resources in our employee recruitment and retention efforts. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. Despite the implementation of security measures, our computer systems and those of third parties with which we contract are vulnerable to damage, including damage from cyberattacks, ransomware attacks, computer viruses, unauthorized access, human error and technological errors, natural disasters and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data 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 our product research, development and commercialization efforts could be delayed. Risks Related to Clinical Development, Regulatory Approval and Commercialization If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, Health Canada (HC) or the European Medicines Agency (EMA), or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization our product candidates. In connection with obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials. In particular, the small number of subjects and patients in early clinical trials of our product candidates may make the results of these clinical trials less predictive of the outcome of later

clinical trials. The design of a clinical trial can determine whether our results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. There is no assurance that we will be able to design and execute a clinical trial to support marketing approval. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Pre- clinical studies or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional pre- clinical studies or clinical trials, or to discontinue clinical trials altogether. Ultimately, we may be unable to complete the development and commercialization of any of our product candidates. ~~30Interim~~ **Interim** results, top- line, initial data may not accurately reflect the complete results of a particular study or trial. We may publicly disclose interim, top- line or initial data from time to time that is based on a preliminary analysis of then- available efficacy and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimates, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Interim, top- line and initial data should be viewed with caution until the final data are available. In addition, the information we may publicly disclose regarding a particular preclinical or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant regarding a particular drug, drug candidate or our business. If the interim, top- line or initial data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed or delayed, which could harm our business, financial condition, operating results or prospects. Any product candidate we advance into and through clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential. Unacceptable adverse events caused by our product candidates in clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale. We have not yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in patients who receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product or, if such product candidate is approved for marketing, future adverse events could cause us to withdraw such product from the market. If clinical trials for our product candidates are prolonged or delayed, we may incur additional costs, and may not be able to commercialize our product candidates on a timely basis or at all. We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials. A number of events, including any of the following, could delay the completion of our ongoing and planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate: ~~●~~ conditions imposed by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials; ~~●~~ delays in obtaining, or the inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials; ~~●~~ insufficient supply or deficient quality of product candidates supply or materials to produce our product candidates or other materials necessary to conduct our clinical trials; ~~●~~ delays in obtaining regulatory agreement for the conduct of the clinical trials; ~~●~~ lower than anticipated enrollment and retention rate of subjects in clinical trials; ~~●~~ serious and unexpected drug- related side effects experienced by patients in clinical trials; ~~●~~ failure of third- party contractors to meet their contractual obligations in a timely manner; ~~●~~ pre- clinical or clinical trials may produce negative or inconclusive results, which may require us or any potential future collaborators to conduct additional pre- clinical or clinical testing or to abandon projects that we expect to be promising; ~~●~~ even if pre- clinical or clinical trial results are positive, the FDA or foreign regulatory authorities could nonetheless require unanticipated additional clinical trials; ~~●~~ regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; ~~●~~ delays in establishing the appropriate dosage levels; ~~●~~ product candidates may not have the desired effects; and ~~●~~ the lack of adequate funding to continue clinical trials. ~~31Additionally~~ **Additionally** , changes in standard of care or regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Such amendments may require us to resubmit our clinical trial protocols to IRBs for re- examination, which may impact the cost, timing or successful completion of a clinical trial. Such changes may also require us to reassess the viability of the program in question. We do not know whether our clinical trials will begin or continue as planned, will need to be restructured or will be completed on schedule, if at all. Delays in clinical trials will result in increased development costs for our product candidates. In addition, if we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our product candidates may be affected and our ability to generate product revenues will be delayed. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. The clinical trial designs, endpoints and outcomes that will be required to obtain marketing approval for our drug candidates are uncertain. We may never receive marketing approval for our drug candidates. To our knowledge, there are currently no FDA- approved drug treatment options specifically approved for many of the disease indications we are targeting with our drug candidates. Accordingly, there may not be well- established development paths and outcomes. The FDA, Health Canada or any other regulatory authority may determine that the designs or endpoints of any trial that we conduct, or that the outcome shown on any particular endpoint in any trial that we conduct, are not sufficient to establish a clinically meaningful benefit for our drug candidates, or otherwise, to

support approval, even if the primary endpoint (s) of the trial is met with statistical significance. If this occurs, our business could be materially harmed. Moreover, if the regulatory authorities require us to conduct additional clinical trials beyond the ones that we currently contemplate, our finances and results from operations will be adversely impacted. If our clinical studies meet their respective primary endpoints, we plan to seek marketing approval. We cannot predict whether each of these regulatory agencies will agree that our study data and information will be sufficient to meet the requirements for filing a marketing application or the standards for approval. If the regulatory agencies determine that more data and information are needed, it could delay and / or negatively impact our ability to obtain regulatory approval to market and sell a particular product candidate. If the commercial opportunity in **vitiligo,** chronic ACD, ARDS, ~~vitiligo~~ or **pulmonary** ~~fibrotic~~ **fibrosis** ~~diseases like systemic sclerosis (SSc)~~ is smaller than we anticipate, our future revenue from our drug candidates will be adversely affected and our business will suffer. It is critical to our ability to grow and become profitable that we successfully identify patients with **vitiligo,** chronic ACD ~~,~~ ARDS ~~, vitiligo~~ or ~~SSc~~ **pulmonary fibrosis** . Our estimates of the number of people who have these conditions as well as the subset who have the potential to benefit from treatment with **EB06,** EB01, EB05 ~~, EB06~~ or EB07, are based on a variety of sources, including third- party estimates and analyses in the scientific literature, and may prove to be incorrect. Further, new information may emerge that changes our estimate of the prevalence of these diseases or the number of patient candidates for these drug candidates. The effort to identify patients for our other potential target indications is at an early stage, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for our drug candidates may be limited or may not be amenable to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. If the commercial opportunity for these conditions is smaller than we anticipate, our future financial performance may be adversely impacted. While we have chosen to test our product candidates in specific clinical indications based in part on our understanding of their mechanisms of action, our understanding may be incorrect or incomplete and, therefore, our product candidates may not be effective against the diseases tested in our clinical trials. Our rationale for selecting the particular therapeutic indications for each of our product candidates is based in part on our understanding of the mechanism of action of these product candidates. However, our understanding of the product candidates' mechanism of action may be incomplete or incorrect, or the mechanism may not be clinically relevant to the diseases treated. In such cases, our product candidates may prove to be ineffective in the clinical trials for treating those diseases, and adverse clinical trial results would likely negatively impact our business and results from operations. Our sPLA2, anti- TLR4 and anti- CXCL10 product candidates employ novel mechanisms of action. To our knowledge no drug companies have successfully commercialized an sPLA2 inhibitor, an anti- TLR4 antibody or an anti- CXCL10 antibody and as a result the efficacy and long- term side effects are not known. There is no guarantee that we will successfully develop and / or commercialize any of these therapies, and / or that our product candidates will have no adverse side effects. ~~32If~~ **If** any product candidate receives marketing approval, the approved product may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If an approved product does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. Our ability to negotiate, secure and maintain third- party coverage and reimbursement for our product candidates may be affected by political, economic and regulatory developments in the U. S., Canada, the EU and other jurisdictions. Governments continue to impose cost containment measures, and third- party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any of our future product candidates that receive marketing approval. We do not have a sales or marketing infrastructure and have no experience as a company in the sale or marketing of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us could be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and any products we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Competitors may also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise than we do. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are approved for broader indications or patient populations, or are more convenient or less expensive than any products that we develop and commercialize. Our competitors may also obtain marketing approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. If approved, our product candidates will compete for a share of the existing market with numerous other products being used to treat ACD, ARDS, vitiligo, SSc or any other indications for which we may receive government approval. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require

approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted and, in some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. ~~33Our~~ -- **Our** ability to commercialize EB01, EB05, EB06, EB07 or any other product candidate successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when and if we begin conducting more expansive clinical development of our product candidates, and we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products manufactured and distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations. We have no direct experience in manufacturing any of our product candidates, and currently lack the resources or capability to manufacture any of our product candidates on a clinical or commercial scale. As a result, we will be dependent on third parties for manufacturing, including optimization, technology transfers and scaling up of clinical scale quantities of all our product candidates. We believe that this strategy will enable us to direct operational and financial resources to the development of our product candidates rather than diverting resources to establishing manufacturing infrastructure; however our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not currently have any agreements with third- party manufacturers for the long- term clinical or commercial supply of any of our product candidates and may in the future be unable to scale- up and / or conclude agreements for commercial supply with commercial third- party manufacturers on acceptable terms, or at all. Even if we are able to establish and maintain arrangements with third- party manufacturers, they may encounter difficulties in achieving volume production, laboratory testing, quality control or quality assurance or suffer shortages of qualified personnel, any of which could result in our inability to manufacture sufficient quantities to meet clinical timelines for a particular product candidate, to obtain marketing approval for the product candidate or to commercialize the product candidate. We may compete with other companies for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. If the third parties that we contract to manufacture product for our preclinical tests and clinical trials cease to continue to do so for any reason or if we elect to change suppliers, we likely would experience delays in advancing these clinical trials while we identify and qualify replacement suppliers and we may be unable to obtain replacement suppliers on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis. ~~34The~~ -- **The** manufacture of our monoclonal antibody candidates requires processing steps that are more complex than those required for most small molecule drugs. As a result of the complexities in manufacturing biologics, the cost to manufacture biologics in general, and our monoclonal antibody candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing processes are less reliable and are more difficult to reproduce. Although we are working with third parties to develop reproducible and commercially viable manufacturing processes for our product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale- out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. We may make changes as we continue to evolve the manufacturing processes for our product candidates for advanced clinical trials and commercialization, and we cannot be sure that even minor changes in these processes will not cause our product candidates to perform differently and affect the results of our ongoing clinical trials, future clinical trials, or the performance of the product once commercialized. In some circumstances, changes in manufacturing operations, including to our protocols, processes, materials or facilities used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements may lead to delays in our clinical development and commercialization plans for our

product candidates, and may increase our development costs substantially. We may also decide to transfer certain manufacturing process know- how and certain intermediates to other contract manufacturing organizations. Transferring manufacturing testing and processes and know- how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. We and any CMOs or third parties that we engage for manufacturing our product candidates will need to conduct significant development work to transfer these processes and manufacture each of our product candidates for clinical trials and commercialization. In addition, we may be required to demonstrate the comparability of material generated by any CMO or third parties that we engage for manufacturing our product candidates with material previously produced and used in testing. The inability to manufacture comparable drug product by us or our CMO could delay the continued development of our product candidates. We also must develop satisfactory methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life. If we fail at any of these tasks, we may not be able to obtain approval or successfully commercialize our product candidates. We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions, drug distributers and clinical investigators, to perform this function. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Our product development costs will increase if we experience delays in testing or obtaining marketing approvals. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials complies with standards, commonly referred to as Good Clinical Practice, and is conducted in accordance with the general investigational plan and protocols for the trial. ~~35If~~ **If** we are not able to establish **or maintain** additional **partnerships or** collaborations, we may have to alter our development and commercialization plans. **The** ~~We may decide to collaborate with pharmaceutical and biotechnology companies for the~~ development **of our product candidates** and **clinical programs and the** potential commercialization ~~of our product candidates~~ **will require substantial additional capital** . ~~Collaborations are complex~~ **Given the high capital requirement for pivotal clinical studies, our preferred strategy is to seek public** and ~~time~~ **private partners for Phase 3 clinical testing and scale** - **up. We** ~~consuming to negotiate and document and we~~ face significant competition in seeking appropriate **partners and** collaborators **. Whether we reach additional definitive agreements for a collaboration or partnership will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or Health Canada, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator or partner may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate** . We may not be able to negotiate collaborations **or partnerships** on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of ~~a~~ product ~~candidate~~ **candidates** , reduce or delay ~~our development program or~~ one or more of our ~~other~~ development programs, delay ~~our~~ potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to **increase our expenditures to** fund development or commercialization activities on our own, we **may** ~~would likely~~ need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, Health Canada and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market EB01, EB05, EB06, EB07 or any other Edesa product candidate from regulatory authorities in any jurisdiction. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and effectiveness. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that EB01, EB05, EB06, EB07 or any of our other product candidates is not effective, is only moderately effective or has undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval or that prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies, clinical trials or other trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates,

the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. Even if marketing approval of a product candidate is granted, an approved product and our manufacturer and marketer are subject to ongoing review and extensive regulation, including the possible requirement to implement a risk evaluation and mitigation strategy or to conduct costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control, quality assurance and documentation. Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post- approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. 36We **We** may not qualify for or ultimately benefit from various expedited regulatory review programs or other special designations. We have obtained a Fast Track designation in the U. S. for EB05 as a treatment for ARDS in critically ill Covid-19 patients, and we may seek additional designations for EB05 or our other product candidates; however, we may never receive such designations. If we believe we meet eligibility requirements, we intend to apply for various regulatory incentives in the U. S., such as breakthrough therapy designation, fast track designation, accelerated approval and priority review, where available, that provide for expedited review and / or other benefits, and we may also seek similar designations elsewhere in the world. Similarly, we may seek orphan drug designation in the U. S. and other jurisdictions for our product candidates, but we may be unable to obtain such designation or to obtain or maintain the benefits associated with orphan drug designation, including market exclusivity. Often, regulatory agencies have broad discretion in determining whether or not product candidates qualify for such regulatory incentives and benefits and we cannot guarantee we would be successful in obtaining beneficial regulatory designations by FDA or other regulatory agencies. Even if approved, expedited designations may not result in faster development processes, reviews or approvals compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may later decide that any of our development programs no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. If we are not able to obtain or maintain such designations for EB05 or other product candidates, it could delay and / or negatively impact our ability to obtain regulatory approval. Regulators have broad discretion regarding emergency use authorizations for medical products, and such authorizations may only be valid during a public health emergency. While, in most cases, a therapeutic must be approved by FDA before the product may be sold, when a public health emergency is declared, subject to certain conditions, FDA may authorize the emergency use of an unapproved medical product under an Emergency Use Authorization (EUA). Similar systems are in place in Canada and the EU. In the event that our clinical study of EB05 is successful, and if we believe we meet eligibility requirements, we intend to submit an application with the regulators for emergency use. Regulators typically do not have review deadlines with respect to such submissions and, therefore, the timing of any potential approval of an emergency use submission would be uncertain. Regulators may refuse to approve our application. In addition, even if granted, the regulators may revoke an emergency use where it is determined that the underlying health emergency no longer exists or warrants such authorization. If we are unsuccessful in obtaining an EUA, or if any granted EUA is revoked after a short period of time, it could have a material adverse effect on our future business, financial condition and operating results. Increasing use of social media platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage. We believe that our potential patient population is active on social media. Social media practices in the pharmaceutical and biotechnology industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, a product candidate, which could result in reporting obligations. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our product candidates on any social networking website. In addition, our employees or third parties with whom we contract, such as our CROs or CMOs, may knowingly or inadvertently make use of social media in a manner that may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers and others or information regarding our product candidates or clinical trials. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our common shares. 37Risks -- **Risks** Related to Our Intellectual Property We are dependent on license relationships with third parties for our key drug development programs. In 2016, we entered into the Yissum License Agreement to obtain exclusive rights to certain know- how, patents and data relating to a pharmaceutical product. We are using the exclusive rights to develop the product for therapeutic, prophylactic and diagnostic uses in topical dermal applications and anorectal applications, including for the development of EB01 to treat ACD and EB02 to treat HD . In 2021, we also entered into the Inventor License Agreement to acquire global rights for all fields of use beyond those named under the Yissum License Agreement. If we default or fail to perform any of the terms, covenants, provisions or our obligations under the Yissum License Agreement, Yissum has the option to terminate the Yissum License Agreement, subject to advance notice to cure such default. Any termination of this license agreement would have a materially adverse impact on our business and results from operations. In April 2020, we entered into the NovImmune License Agreement to obtain exclusive rights throughout the world to certain know- how, patents and data relating to the monoclonal antibodies

targeting TLR4 and CXCL10. We are using these rights to develop EB05 as a potential treatment for ARDS and other disease indications. If we default or fail to perform any of the terms, covenants, provisions or our obligations under the NovImmune License Agreement, including milestone payments, NovImmune has the option to terminate the NovImmune License Agreement, subject to advance notice to cure such default. Any termination of this license agreement would have a materially adverse impact on our business and results from operations. Our success will partially depend on our ability to obtain and maintain patent protection in the U. S. and other countries with respect to our proprietary technology and products. We intend to protect our proprietary position by filing patent applications in the U. S., in Europe and in certain additional jurisdictions related to our novel technologies and product candidates that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, if we license technology or product candidates from third parties in the future, these license agreements may not permit us to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering the licensed technology or product candidates. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents issued to us will likely be highly uncertain. Patent applications that we file may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U. S. and other countries may also diminish the value of patents issued to us, narrow the scope of our patent protection or make enforcement more difficult or uncertain. We may become involved in lawsuits or other enforcement proceedings to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and potentially unsuccessful. Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file claims, which can be expensive and time consuming to prosecute. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property or that our patent and other intellectual property rights are invalid or unenforceable, including for antitrust reasons. As a result, in a patent infringement proceeding, a court or administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, or may construe the patent' s claims narrowly and so refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the competitor technology in question. Even if we are successful in a patent infringement action, the unsuccessful party may subsequently raise antitrust issues and bring a follow- on action thereon. Antitrust issues may also provide a bar to settlement or constrain the permissible settlement terms. ~~38Third~~ -- **Third** parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. The risks of being involved in such litigation and office proceedings may also increase as our product candidates approach commercialization, and as our business gains greater visibility. Third parties may assert infringement claims against us based on existing or future intellectual property rights and to restrict our freedom to operate. Third parties may also seek injunctive relief against us, whereby they would attempt to prevent us from practicing our technologies altogether pending outcome of any litigation against us. We may not be aware of all such intellectual property rights potentially relating to our product candidates prior to their assertion against us. If we are found to infringe a third party' s intellectual property rights, we could incur substantial monetary damages. A finding of infringement could also prevent us from commercializing our product candidates, lose market exclusivity, require substantial license payments, or force us to cease some of our business operations, which could materially harm our business. Intellectual property litigation could cause us to spend substantial resources and could distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and likely would distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments that could have a substantial adverse effect on the price of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, costs and lost management time, as well as uncertainties resulting from the initiation and continuation of patent litigation or other proceedings, could have a material adverse effect on our ability to compete in the marketplace. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We partially rely on trade secrets and know- how, including unpatented know- how, technology and other proprietary and confidential information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary or confidential information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is

unpredictable. In addition, some courts inside and outside the U. S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, particularly unpatented know- how, were to be obtained or independently developed by a competitor, our competitive position would be harmed. Risks Related to Owning Our Securities The price of our common shares may continue to be volatile. Market prices for securities of clinical- stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile, and the market price of our common shares has been subject to significant fluctuations. This volatility can be exacerbated by low trading volume. Some of the factors that may cause the market price of our shares to fluctuate include: ~~-~~ ● sales or potential sales of substantial amounts of our common shares; ~~-~~ ● announcements about us or our competitors, including funding announcements, corporate or business updates, updates on manufacturing of our products, clinical trial results, regulatory approvals or new product introductions; ~~-~~ ● developments concerning our product manufacturers; ● ~~39 -~~ litigation and other developments relating to our licensed patents or other proprietary rights or those of our competitors; ~~-~~ ● governmental regulation and legislation; ~~-~~ ● change in securities analysts' estimates of our performance, or failure to meet analysts' expectations; ~~-~~ ● the terms and timing of any future collaborative, licensing or other arrangements that we may establish; ~~-~~ ● our ability to raise additional capital to carry through with our development plans and current and future operations; ~~-~~ ● the timing of achievement of, or failure to achieve, our manufacturing, pre- clinical, clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval; ~~-~~ ● actions taken by regulatory agencies with respect to our product candidates; ~~-~~ ● uncontemplated problems in the supply of the raw materials used to produce our product candidates; ~~-~~ ● introductions or announcements of technological innovations or new products candidates by us, our potential future collaborators, or our competitors, and the timing of these introductions or announcements; ~~-~~ ● market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular; ~~-~~ ● actual or anticipated fluctuations in our results of operations; ~~-~~ ● hedging or arbitrage trading activity that may develop regarding our common shares; ~~-~~ ● regional or worldwide recession; ~~-~~ ● sales of our common shares by our executive officers, directors and significant shareholders; ~~-~~ ● changes in accounting principles; and ~~-~~ ● the loss of any of our key scientific or management personnel. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common shares. In the past, following periods of volatility in the market price of a company' s securities, shareholders have often instituted class action securities litigation. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. ~~If we fail to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common shares, the delisting could adversely affect the market liquidity of our common shares and the market price of our common shares could decrease and our ability to access the capital markets could be negatively impacted.~~ Our common shares are listed on The Nasdaq Capital Market. We must satisfy the continued listing requirements of Nasdaq, to maintain the listing of our common shares on The Nasdaq Capital Market. ~~As previously reported, on June 22, 2023, we received notice from Nasdaq' s Listing Qualifications Staff indicating that, based upon the closing bid price of our common shares for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of $ 1. 00 per share for continued listing on Nasdaq, as set forth in Nasdaq Listing Rule 5550 (a) (2) (the Bid Price Rule). We had 180 days, or through December 19, 2023, to regain compliance with the Bid Price Rule. On October 11, 2023, we effected a one- for- seven reverse split of our common shares. By letter dated October 25, 2023, Nasdaq advised us that we had regained compliance with the Bid Price Rule.~~ There can be no assurance that we will be able to continue to maintain compliance with the Nasdaq continued listing requirements, and if we are unable to maintain compliance with the continued listing requirements ~~, including the Bid Price Rule~~ , our securities may be delisted from Nasdaq, which could reduce the liquidity of our common shares materially and result in a corresponding material reduction in the price of our common shares. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees, suppliers and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common shares when you wish to do so. Further, if we were to be delisted from Nasdaq, our common shares may no longer be recognized as a " covered security " and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common shares. ~~40We~~ **We** do not currently intend to pay dividends on our common shares in the foreseeable future, and consequently, any gains from an investment in our common shares will likely depend on appreciation in the price of our common shares. We have never declared or paid cash dividends on our common shares and do not anticipate paying any cash dividends to holders of our common shares in the foreseeable future. Consequently, investors must rely on sales of their common shares and warrants after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that our common shares will appreciate in value or even maintain the price at which the shareholders have purchased their shares. A sale of a substantial number of our common shares in the public market could cause the market price of our common shares to drop significantly, even if our business is doing well. The price of our common shares could decline as a result of sales of a large number of our common shares or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. In addition, in the future, we may issue additional common shares, warrants or other equity or debt securities convertible into common shares in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause the price of our common shares to

decline. If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common shares, the price of our common shares could decline. The trading market for our common shares relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common shares could decline if one or more equity analysts downgrade our common shares or if analysts issue other unfavorable commentary or cease publishing reports about us or our business. Our **directors and executive officers have control over us and could delay or prevent a change of corporate control. As of December 11, 2024, Dr. Nijhawan, our Chief Executive Officer, beneficially owns 19. 99 % of our outstanding common shares and all of our executive officers and directors, including Dr. Nijhawan, beneficially own 23. 9 % of our common shares. As a result, such individuals will have the ability, acting together, to significantly influence the election of our directors and the outcome of corporate actions requiring shareholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our Articles. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other shareholders and be disadvantageous to our shareholders with interests different from those individuals. See " Security Ownership of Certain Beneficial Owners and Management " below for more information regarding the ownership of our outstanding common shares by our executive officers, directors and holders of more than 5 % of our common stock, together with their affiliates. Our** Articles allow for our board of directors to create new series of preferred shares without further approval by the shareholders, which could adversely affect the rights of the holders of our common shares. As previously approved by our shareholders, our board of directors **(" Board ")** has the authority to authorize up to an unlimited number of a new series of our preferred shares and to fix and determine the special rights and restrictions of that series without further shareholder approval, subject to the terms set out in the Articles and unless otherwise required by the Business Corporations Act (British Columbia). As a result, our board of directors could authorize the creation of a series of our preferred shares that would grant to holders of the preferred shares a right to our assets upon liquidation before a distribution to the holders of our common shares. In addition, our board of directors could authorize the creation of a new series of our preferred shares that is convertible into our common shares, which could result in dilution to existing shareholders **. On October 30, 2024, we filed Amended Articles to amend the rights, preferences, restrictions and other matters pertaining to our newly designated Series A- 1 Convertible Preferred Shares (the " Preferred Shares "). The Preferred Shares have no par value and a stated value of $ 10, 000 per share and rank, with respect to redemption payments, rights upon liquidation, dissolution or winding- up of the Company, or otherwise, senior in preference and priority to our common shares. Our common shares rank junior to the preferred shares in the event of a liquidation, dissolution or winding- up of the Company. In the event of any liquidation, dissolution or winding- up of the Company, a holder of the Preferred Shares will be entitled to receive, before any distribution or payment may be made with respect to the holders of our common shares, an amount equal to 100 % of the stated value, plus a return equal to 10 % of the stated value per Preferred Share per annum, calculated daily. Any issuance of our common shares upon conversion of the Preferred Shares will cause dilution to our then existing stockholders and may depress the market price of our common shares. The Preferred Shares accrue an annual return equal to 10 % of the stated value per Preferred Share payable by the issuance of our common shares at the conversion price upon a buy- back by the Company, liquidation or on conversion at the conversion price (calculated daily). Each Preferred Share is convertible into a number of our common shares calculated by dividing (i) the sum of the stated value of such Preferred Share plus a return equal to 10 % of the stated value per Preferred Share per annum, calculated daily, by (ii) a fixed conversion price of $ 3. 445. The issuance of our common shares upon conversion of the Preferred Shares will result in immediate and substantial dilution to the interests of holders of our common shares, and such dilution will increase over time in connection with the accrual of the annual return on the Preferred Shares. We may incur future indebtedness that will rank senior to the Preferred Shares or issue additional series of preferred shares that rank on a parity with, or senior to, the Preferred Shares as to dividend payments and liquidation preference. We may incur substantial amounts of additional debt and other obligations that will rank senior to the Preferred Shares, and the terms of the Preferred Shares do not limit the amount of such debt or other obligations that we may incur. The terms of the Preferred Shares will not prohibit us from issuing additional series of preferred shares that would rank on parity with the Preferred Shares. The Articles allow for our board of directors to create new series of preferred shares without further approval by our shareholders, which could adversely affect the rights of the holders of the Preferred Shares and our common shares. The issuances of other series of preferred shares could have the effect of reducing the amounts available to the Preferred Shares in the event of liquidation. If we issue preferred shares with voting rights that dilute the voting power of our common shares, the market price of our common shares could decrease, adversely affecting the value of the Preferred Shares. Additional issuances and sales of preferred shares, or the perception that such issuances and sales could occur, may cause prevailing market prices for our common shares to decline and may adversely affect our ability to raise additional capital in the financial markets at times and prices favorable to it** . Failure to maintain effective internal control over financial reporting could have a material adverse effect on our share price. Section 404 of the Sarbanes- Oxley Act of 2002 and the related rules and regulations of the SEC require an annual management assessment of the effectiveness of our internal control over financial reporting. As a smaller reporting company as defined in Rule 12b- 2 under the Exchange Act, we are currently exempt from the auditor attestation requirement of Section 404 (b). If we lose this eligibility, we will incur increased personnel and audit fees in connection with the additional audit requirements. If we fail to maintain the adequacy of our internal control over financial reporting, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act of 2002 and the related rules and regulations of the SEC. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in

the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness or significant deficiencies in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also adversely affect investor confidence in the reliability of our financial reports and restrict our future access to the capital markets. ~~41The~~ -- **The** ownership of our common shares is highly concentrated among insiders and affiliates. Accordingly, these shareholders will have substantial influence over the outcome of corporate actions requiring shareholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company' s assets or any other significant corporate transaction. These shareholders may also delay or prevent a change of control of the Company, even if such a change of control would benefit the other shareholders of the Company. The significant concentration of share ownership may adversely affect the trading price of our common shares due to investors' perception that conflicts of interest may exist or arise. We may be deemed a passive foreign investment company, and as a result, U. S. shareholders may be subject to special taxation rules that restrict capital gains treatment, unless the shareholders make a timely tax election to treat the company as a qualified electing fund. A special set of U. S. federal income tax rules applies to a foreign corporation that is deemed a passive foreign investment company (PFIC) for U. S. federal income tax purposes. Based on our audited financial statements, income tax returns, and relevant market and shareholder data, we believe that we likely will not be classified as a PFIC in the September 30, ~~2023~~ **2024** taxable year. There can be no assurance, however, that we will not be considered to be a PFIC for any particular year in the future because PFIC status is factual in nature, depends upon factors not wholly within our control, generally cannot be determined until the close of the taxable year in question, and is determined annually. If we are deemed to be a PFIC during the current or a future taxable year, U. S. shareholders would be subject to special taxation rules related to gain on sale or disposition of our shares and excess distributions unless they make a timely election to treat our shares as a qualified electing fund (QEF election). A QEF election cannot be made unless we provide U. S. shareholders the information and computations needed to report income and gains pursuant to a QEF election. Without a QEF election, U. S. shareholders may not be able to use capital gains tax treatment and may be subject to potentially adverse tax consequences. Given the complexities of the PFIC and QEF election rules, U. S. shareholders may need to incur the time and expense of consulting a tax adviser about these rules.