Risk Factors Comparison 2024-04-01 to 2023-03-30 Form: 10-K

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Summary of our Risks: Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled " Risk Factors " in this Form 10- K. These risks include, among others: ~~*~~ **● If we fail to regain compliance with the continued listing requirements of Nasdaq, our Common Stock may be delisted and the price and liquidity of our common stock may be negatively impacted. ● We are and could be further subject to securities class action litigation and other types of stockholder litigation. ●** We will need substantial additional funding to pursue our business objectives and continue our operations. If we are unable to raise capital when needed, we may be required to delay, limit, reduce or terminate our research or product development efforts or future commercialization efforts. ~~*~~ ● We have a history of losses and we expect to incur losses for the foreseeable future. ~~*~~ ● The continuing effects of the novel coronavirus disease, COVID- 19, including the emergence of new variants, could adversely impact our business, including our clinical trials and supply chain. ~~*~~ ● Our product development programs are based on novel technologies and are inherently risky. The field of stem cell therapy is relatively new and our development efforts may not yield an effective treatment of human diseases. ~~*~~ ● Our NurOwn ® stem cell therapy may not demonstrate safety and efficacy sufficient to obtain regulatory approval, and may not receive regulatory approval. Our NurOwn ® stem cell therapy, even if approved, may not be accepted in the marketplace; therefore, we may not be able to generate significant revenue, if any. ~~*~~ ● If serious or unexpected adverse side effects are identified during the development of our NurOwn ® stem cell therapy, we may need to abandon or limit its development. ~~*~~ ● Our success will depend in part on establishing and maintaining effective strategic partnerships and collaborations, which may impose restrictions on our business and subject us to additional regulation. ~~*~~ ● We have never manufactured our NurOwn ® stem cell therapy at commercial scale and there can be no assurance that it can be manufactured in compliance with regulations at a cost or in quantities necessary to make it commercially viable. ~~*~~ ● Part of our business in the foreseeable future will be based on technology licensed from Ramot and if this license were to be terminated upon failure to make required royalty payments in the future, we would need to change our business strategy and we may be forced to cease our operations. ~~*~~ ● Technological and medical developments or improvements in conventional therapies could render the use of stem cells and our services and planned products obsolete. ~~*~~ ● We face substantial competition in developing cell therapies for ALS and other neurodegenerative diseases, which may result in others discovering, developing or commercializing products before or more successfully than we do. ~~*~~ ● It is uncertain to what extent the government, private health insurers and third- party payors will approve coverage or provide reimbursement for the therapies and products to which our services relate. Availability for such reimbursement may be further limited by an increasing uninsured population and reductions in Medicare and Medicaid funding in the United States. ~~*~~ ● We are exposed to fluctuations in currency exchange rates. The dollar cost of our operations in Israel will increase to the extent increases in the rate of inflation in Israel are not offset by a devaluation of the NIS in relation to the dollar, which would harm our results of operations. ~~Risks Related~~ **● Political, economic and military instability in Israel may impede our ability** to **execute our plan of operations. For example, due to** the ~~COVID~~ **Israel** - **Hamas war** ~~19 PandemicContinuing concerns resulting from the pandemic of COVID- 19~~ and **/ or** ~~the future outbreak of~~ other **military conflicts with Lebanon** ~~highly infectious or contagious diseases~~ , **Syria, Iran** ~~could have a material adverse impact on our~~ - **or** ~~business, financial condition and results of~~ **other hostile countries may lead to difficulties in bringing** ~~operations~~ **operational personnel** ~~, including our preclinical studies~~ and **equipment into** ~~clinical trials. Continuing concerns resulting from the pandemic caused by the novel strain of coronavirus, SARS- CoV 2 (COVID- 19) disease, including the emergence of new variants, has currently impacted and may continue to adversely impact our business, including our preclinical studies and clinical trials. In December 2019, a novel strain of coronavirus, surfaced in Wuhan, China. Since then, COVID- 19 has spread worldwide, significantly impacting the United States, Europe and~~ Israel ~~, where the Company conducts its operations, as well as its clinical trials for NurOwn ®. In response to the spread of COVID- 19 and to ensure safety of employees and continuity of business operations, we closed our offices, with our administrative employees continuing their work remotely and limited the number of staff in any given research and development laboratory. Our research and development laboratory in Israel and manufacturing sites in U. S. and in Israel remain open. The full extent to which the COVID- 19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted at this time, including new information that may emerge concerning COVID- 19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Our management team is actively monitoring this situation and the possible effects on our financial condition, liquidity, operations, suppliers, industry, and workforce. We completed dosing of all participants in our Phase 3 ALS trial in July 2020, and we announced top- line data from this trial on November 17, 2020. Results from the trial showed that NurOwn ® was generally well tolerated in the population of rapidly progressing ALS patients. While showing a numerical improvement in the treated group compared to placebo across the primary and key secondary efficacy endpoints, the trial did not reach statistically significant results. In an important, pre- specified subgroup with early disease based on ALS Functional Rating Score (" ALSFRS- R ") baseline score 35, NurOwn ® demonstrated a clinically meaningful treatment response across the primary and key secondary endpoints and remained consistent with our pre- trial, data- derived assumption. In this subgroup, there were 34. 6 % responders who met the primary endpoint definition on NurOwn ® and 15. 6 % on Placebo (p = 0. 288), and the average change from baseline to week 28 in ALSFRS- R total score was- 1. 77 on NurOwn ® and- 3. 78 on Placebo (p = 0. 198), an improvement of 2. 01 ALSFRS- R points favoring NurOwn ®. When~~

~~following the SAP to implement sensitivity to the primary endpoint, there is a slight change in the percentage of responders but no P value change. No new safety concerns were identified. Following the completion of our phase 3 ALS trial, we are diligently pursuing next steps, including active discussions with the FDA to identify regulatory pathways that may support NurOwn ®' s approval in ALS. We are also in active dialog with the FDA around our Chemistry, Manufacturing and Controls (CMC) plans for registration, and completed a successful meeting in December 2020. The U. S. Phase 2 PMS trial faced slight delays in enrollment due to the COVID- 19 pandemic, but as of June 2020, all the trial sites were back on track to continue with the trial. On December 18, 2020, we announced the completion of all dosing in the study participants in the trial and positive top- line clinical trial results were announced on March 24, 2021. During a public health emergency, certain manufacturing facilities and materials may be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Further, during a public health emergency, the FDA and other foreign regulatory authorities may be unable to ensure timely reviews of applications for medical products. During the COVID- 19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications~~ . Risks Related to our Financial Condition and Capital RequirementsWe need to raise additional capital. If we are unable to raise additional capital in favorable terms and a timely manner, we will not be able to execute our business plan and we could be forced to restrict or cease our operations. We will need to raise additional funds to meet our anticipated expenses so that we can execute our business plan. We expect to incur substantial and increasing net losses for the foreseeable future as we increase our spending to execute our development and commercial programs. The amount of financing required will depend on many factors including our financial requirements to fund any additional research and clinical trials, our ability to secure partnerships and achieve partnership milestones and our ability to establish manufacturing and ~~45delivery~~ **delivery** processes for our NurOwn ® stem cell therapy as well as to fund other working capital requirements. Our ability to access the capital markets or to enlist partners is mainly dependent on the progress of our research and development and regulatory approval of our products. To date, the Company has not generated revenues from its activities and has incurred substantial operating losses. Management expects the Company to continue to generate substantial operating losses and to continue to fund its operations primarily through utilization of its current financial resources and through additional raises of capital. Management' s plan includes raising funds from outside potential investors, including under the ATM Program. However, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. Should we raise additional funds through the issuance of equity, equity- related or debt securities, these securities may have rights, preferences or privileges (including registrations rights) senior to those of the rights of our Common Stock and our stockholders will experience additional dilution. We have a history of losses and we expect to incur losses for the foreseeable future. As a development stage pre- revenue company, we are in the early stages of executing our business plan. We had no operational revenues for the fiscal years ended December 31, 2020, December 31, 2021 ~~or~~ December 31, 2022 **, or December 31, 2023** . We are currently in the process of introducing the Company to strategic partners. In **2024 and** the upcoming ~~three~~ years, the Company will focus on **initiating and** completing ~~its ongoing clinical~~ **a Phase 3b** ~~trials~~ **trial** and commercialization of NurOwn ® for ALS, if approved. We are unable, at this time, to foresee when we will generate operational revenues from strategic partnerships. If NurOwn ® is approved by the FDA for ALS, we hope to commercialize and start generating revenues shortly thereafter. ~~,~~ We expect to incur substantial and increasing operating losses for the next several years as we increase our spending to execute our development programs and commercialization efforts. These losses are expected to have an adverse impact on our working capital, total assets and stockholders' equity. We are exposed to fluctuations in currency exchange rates. A significant portion of our business, particularly our research and development, is conducted outside the United States. Therefore, we are exposed to currency exchange fluctuations in other currencies such as the New Israeli Shekels (" NIS ") and the Euro. Moreover, a portion of our expenses in Israel and Europe are paid in NIS and Euros, respectively, which subjects us to the risks of foreign currency fluctuations. Our primary expenses paid in NIS are employee salaries, fees for consultants and subcontractors and lease payments on our Israeli facilities. ~~The~~ **43The** dollar cost of our operations in Israel will increase to the extent increases in the rate of inflation in Israel are not offset by a devaluation of the NIS in relation to the dollar, which would harm our results of operations. Since a considerable portion of our expenses such as employees' salaries are linked to an extent to the rate of inflation in Israel, the dollar cost of our operations is influenced by the extent to which any increase in the rate of inflation in Israel is or is not offset by the devaluation of the NIS in relation to the dollar. As a result, we are exposed to the risk that the NIS, after adjustment for inflation in Israel, will appreciate in relation to the dollar. In that event, the dollar cost of our operations in Israel will increase and our dollar- measured results of operations will be adversely affected. During the past few years inflation- adjusted NIS appreciated against the dollar, which raised the dollar cost of our Israeli operations. We cannot predict whether the NIS will appreciate against the dollar or vice versa in the future. Any increase in the rate of inflation in Israel, unless the increase is offset on a timely basis by a devaluation of the NIS in relation to the dollar, will increase labor and other costs, which will increase the dollar cost of our operations in Israel and harm our results of operations. Risks Related to our Cell Therapy Product Development EffortsIf our NurOwn ® stem cell therapy does not demonstrate safety and efficacy sufficient to obtain regulatory approval, it may not receive regulatory approval and we will be unable to market it. The therapeutic treatment development and regulatory approval process is expensive, uncertain and time- consuming. As part of the regulatory process, we conduct clinical trials, for our NurOwn ® stem cell therapy to demonstrate safety and efficacy in humans to meet the requirements of the FDA and regulatory authorities in other countries. We have completed our Phase 3 ALS trial and announced on February 2021 that the FDA concluded from their initial review that the current level of clinical data does not provide the threshold of ~~46substantial~~ **substantial** evidence that FDA is seeking to support a BLA. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA. The FDA indicated that we could request a

Type A meeting to discuss the content of the RTF letter, and the Type A meeting was held on January 11, 2023. We notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn ® BLA for ALS over Protest. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. Written notification was received on March 22, 2023 from the FDA project manager associated with the BLA confirming the FDA' s decision to grant an ADCOM for the NurOwn ® BLA for ALS. ~~The~~ **On September 27, 2023, we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn ® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On October 18, 2023, we announced that the FDA invited the Company to request an expedited face- to- face meeting to discuss the path forward for NurOwn ® as a treatment for ALS. BrainStorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn ®, including publication of emerging clinical data and development of a protocol for an additional clinical study. On October 18, 2023 Brainstorm announced that the** BLA for NurOwn **® would be withdrawn. The BLA was withdrawn on November 3, 2023. The decision** to ~~treat~~ **withdraw the BLA was coordinated with the FDA and is viewed by the FDA as a withdrawal without prejudice. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn ® in** ALS **. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn ®. The primary objective of the meeting was to discuss plans for a SPA with the FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn ®. As an outcome of the meeting, BrainStorm will submit relevant documentation as outlined by the FDA to support the SPA. The ultimate goal of the SPA** is **to secure** ~~currently under active review by~~ the FDA **' s agreement that critical elements of the overall protocol design (e. g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn ® for the treatment of ALS** . If we fail to obtain regulatory approval for our NurOwn ® stem cell therapy, we will be unable to market and sell it and we may never be profitable. A failure of one or more of our clinical trials can occur at any stage of testing. Results of later stage clinical trials may fail to show the desired safety and efficacy despite acceptable results in earlier clinical trials. 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 and clinical trials have nonetheless failed to obtain marketing approval of their treatments. Specifically, we are currently comparing NurOwn ® stem cell therapy against placebo. Comparisons of outcomes of other reported clinical trials may provide some insight into the efficacy of NurOwn ® stem cell therapy, however, these studies may be of limited comparative value due to the many factors that affect the outcome of clinical trials, some of which are not apparent in published reports. ~~Additionally~~ **44Additionally** , several of our past, planned and ongoing clinical trials utilize an " open- label " trial design. An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open- label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open- label clinical trial when studied in a controlled environment with a placebo or active control. Our product development programs are based on novel technologies and are inherently risky. We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our autologous stem cell therapy creates significant challenges with regard to product development and optimization, manufacturing, government regulations, and market acceptance. For example, although cell therapy has been available in oncology, the FDA' s experience with mesenchymal stem cell therapies is limited. None have been approved by the FDA for commercial sale in the US, and the pathway to regulatory approval for our stem cell therapies may accordingly be more complex and lengthy. As a result, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs. If serious or unexpected adverse side effects are identified during the development of our NurOwn ® stem cell therapy, we may need to abandon or limit its development. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by NurOwn ® could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. If patients treated with our NurOwn ® stem cell therapy suffer serious or unexpected adverse effects, we may need to abandon its development or limit development to certain uses or subpopulations in which these effects are less prevalent, less severe or more acceptable from a risk- benefit perspective. Any of these occurrences may harm our business, financial condition and prospects significantly. ~~47Despite~~ -- **Despite** our experience conducting and managing clinical trials, we may not be able to conduct and manage future trials successfully and have limited experience in the application process necessary to obtain regulatory approvals. Despite our prior experience in conducting and managing clinical trials, we may not be able to conduct and manage future trials successfully. We have limited experience in the application process to obtain regulatory approvals. If our clinical trials are unsuccessful, or if we do not complete our clinical trials, we may not receive regulatory approval for or be able to commercialize our stem cell therapies. If we do not succeed in conducting and managing our preclinical development activities

or clinical trials, or in obtaining regulatory approvals, we might not be able to commercialize our stem cell therapies, or might be significantly delayed in doing so, which will materially harm our business. Our ability to generate revenues from any of our stem cell therapies will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and implement our commercialization strategy. We may, and anticipate that we will need to, transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not succeed in such a transition. ~~We~~ **45We** may not be able to secure and maintain research institutions to conduct our clinical trials. We rely on research institutions to conduct our clinical trials. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreements with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. Furthermore, we may not be able to secure and maintain suitable research institutions to conduct our clinical trials. Risks Related to Our Business Operations and Commercialization of Stem Cell TherapiesThe field of stem cell therapy is relatively new and our development efforts may not yield an effective treatment of human diseases. Our intended cell therapeutic treatment NurOwn ® for ALS involves a new approach using stem cells to treat ALS. Cell therapy is still a developing area of research, with few cell therapy products approved for clinical use. Many of the existing cellular therapy candidates are based on novel cell technologies that are inherently risky and may not be understood or accepted by the marketplace. The novel nature of our cell therapy technology creates significant challenges with respect to product development and optimization, manufacturing, government regulation and approval, third- party reimbursement. Our NurOwn ® stem cell therapy, even if approved, may not be accepted in the marketplace; therefore, we may not be able to generate significant revenue, if any. Even if our NurOwn ® stem cell therapy is approved for sale, physicians and the medical community may not ultimately use it or may use it only in applications more restricted than we anticipate. Our NurOwn ® stem cell therapy, if successfully developed, will compete with a number of traditional products manufactured and marketed by major pharmaceutical and biotechnology companies. Our NurOwn ® stem cell therapy may also compete with new products currently under development by such companies and others. Physicians will prescribe a treatment only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently available and in use. Physicians also will prescribe a product based on their traditional preferences. Many other factors influence the adoption of new products, including patient perceptions and preferences, marketing and distribution restrictions, adverse publicity, product pricing, views of thought leaders in the medical community and reimbursement by government and private payors. Any of these factors could have a material adverse effect on our business, financial condition, and results of operations. ~~48Adoption~~ -- **Adoption** of our NurOwn ® stem cell therapy for the treatment of patients with ALS, PMS, AD or other neurodegenerative diseases, even if approved, may be slow or limited. If our NurOwn ® stem cell therapy does not achieve broad acceptance as a treatment option for ALS, PMS, AD or other neurodegenerative diseases, our business would be negatively impact our revenue forecast. If approved, the rate of adoption of our NurOwn ® stem cell therapy as a treatment for ALS, PMS, AD or other neurodegenerative diseases, and the ultimate sales volume for our treatment, will depend on several factors, including educating treating physicians on how to use our NurOwn ® stem cell therapy. Our NurOwn ® stem cell therapy utilizes individualized stem cell therapy, which is significantly different from the pharmacological approach currently used to treat neurodegenerative diseases. Acceptance of our NurOwn ® stem cell therapy by physicians may require us to provide them with extensive education regarding the mechanism of action of our treatment, the method of delivery of the treatment, expected side effects and the method of monitoring patients for efficacy and follow- up. In addition, the manufacturing and delivery processes associated with our treatment will require physicians to adjust their current treatment of patients, which may delay or prevent market adoption of our NurOwn ® stem cell therapy as a preferred therapy, even if approved. Our success will depend in part on establishing and maintaining effective strategic partnerships and collaborations, which may impose restrictions on our business and subject us to additional regulation. A key aspect of our business strategy is to establish strategic relationships to expand or complement our research and development or commercialization capabilities, and to reduce the cost of such activities. There can be no assurance that we will enter into such relationships, that the arrangements will be on favorable terms or that such relationships will be successful. If we are ultimately successful in executing our strategy of securing collaborations with companies that would undertake advanced clinical development and commercialization of our products, we may not have day- to- day control over their activities. Potential collaborators may have significant discretion in determining the efforts and amount of resources that they dedicate to our collaborations or may be unwilling or unable to fulfill their obligations to us, including their development and commercialization. Potential collaborators may underfund or not commit ~~sufficient~~ **46sufficient** resources to the testing, marketing, distribution or other development of our products. They may also not properly maintain or defend our intellectual property rights or they may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability. Potential collaboration partners may have the right to terminate the collaboration on relatively short notice and if they do so or if they fail to perform or satisfy their obligations to us, the development or commercialization of products may be delayed and our ability to realize any potential milestone payments and royalty revenue would be adversely affected. We will need to develop or acquire additional capabilities in order to commercialize our NurOwn ® stem cell therapy, if approved for sale, and we may encounter unexpected costs or difficulties in doing so. We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and, if our NurOwn ® stem cell therapy receives regulatory approval, commercialization efforts. Currently, we have no experience in commercial- scale manufacturing, managing of large-scale information technology systems or managing a large- scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. To do this effectively, we must: ~~*~~ ● train, manage and motivate a growing employee base; ~~*~~ ● accurately forecast demand for our

treatment; and * ● expand existing operational, financial and management information systems. We expect to expand our development, regulatory, manufacturing and sales and marketing 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, which could be** significant ~~growth~~ in ~~the number of our employees~~ **nature as we near regulatory approval,** and the scope of our operations, particularly in the areas of product development, regulatory affairs, manufacturing and 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. Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, 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. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. ~~49We~~ **We** have never manufactured our NurOwn ® stem cell therapy at commercial scale and there can be no assurance that it can be manufactured in compliance with regulations at a cost or in quantities necessary to make it commercially viable. Although, several members of our management team have experience in commercial scale cell therapy manufacturing, we have no experience in commercial- scale stem cell therapy manufacturing. We may develop our manufacturing capacity in part by expanding our current facilities and / or by setting up additional facilities in other regions of the country. These activities would require substantial additional funds and we would need to hire and train significant numbers of qualified employees to staff these facilities. ~~To this end, we are working with Catalent, a third party manufacturer for producing commercial quantities of NurOwn ® to treat patients with Neurodegenerative disease. We are also working with RR & D, to help us establish in- house manufacturing capabilities. Our current dependence on others for the manufacture of our drug candidates may adversely affect our ability to develop and deliver such drug candidates on a timely and competitive basis. For our product candidates that are biologic- device combination products, third- party manufacturers may not be able to comply with cGMP regulatory requirements applicable to biologic- device combination products, including applicable provisions of the FDA' s drug product cGMP regulations, device cGMP requirements embodied in the FDA' s Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Any performance failure on the part of a third- party manufacturer could delay clinical development, regulatory approval or, ultimately, sales of our NurOwn ®. Our third- party manufacturers may encounter difficulties involving production yields, regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. Approval of our NurOwn ® could be delayed, limited or denied if the FDA does not approve our or a third- party manufacturer' s processes or facilities.~~ If any contract manufacturing organization ~~, or~~ **(“** CMO **”)** with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another ~~CMO~~ **47CMO** manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. In addition, in response to the COVID- 19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities while local, national and international conditions warrant. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre- approval inspections on a prioritized basis. Should **the** FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID- 19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to the ongoing COVID- 19 pandemic or future epidemics and may experience delays in their regulatory activities. If we are not successful in establishing regulatory compliant, scaled manufacturing capabilities, our commercialization could be delayed, which would further delay the period when we would be able to generate revenues from the sale of such of our products. Furthermore, we must supply all necessary documentation, including product characterization and process validation, to regulatory authorities in support of our BLA on a timely basis and must adhere to cGMP and cGTP regulations enforced by the regulatory authority through its facilities inspection program. If the FDA determines that the products used in our clinical trials are not sufficiently ~~50characterized~~ -- **characterized** , we may be required to repeat all or a portion of our clinical trials. If our facilities cannot pass a pre- approval plant inspection, the regulatory approval of the stem cell therapies will not be granted.

Lack of coordination internally among our employees and externally with physicians, hospitals and third- party suppliers and carriers, could cause manufacturing difficulties, disruptions or delays and cause us to not meet our expected clinical trial requirements or potential commercial requirements. Manufacturing our NurOwn ® stem cell therapy requires coordination internally among our employees and externally with physicians, hospitals and third- party suppliers and carriers. For example, a patient' s physician or clinical site will need to coordinate with us for the shipping of a patient' s bone marrow to our manufacturing facility, and we will need to coordinate with them for the shipping of the treatment components to them. Such coordination involves a number of risks that may lead to failures or delays in manufacturing our NurOwn ® stem cell therapy, including: ~~*~~ ● failure to obtain a sufficient supply of key raw materials of suitable quality; ~~*~~ ● difficulties in manufacturing our stem cell therapies for multiple patients simultaneously; ~~*~~ ● difficulties in obtaining adequate patient- specific material, such as bone marrow samples, from physicians; ~~*~~ ● difficulties in completing the development and validation of the harvested cells required to ensure the consistency of our NurOwn ® stem cell therapy; ~~*~~ ● failure to ensure adequate quality control and assurances in the manufacturing process as we increase production quantities; ~~*~~ ● difficulties in the timely shipping of patient- specific materials to us or in the shipping of the stem cell therapies to the treating physicians due to errors by third- party carriers, transportation restrictions or other reasons; ~~*~~ ● loss or destruction of, or damage to, patient- specific materials or our NurOwn ® stem cell therapy during the shipping process due to improper handling by third- party carriers, hospitals, physicians or us; ~~*~~ ● loss or destruction of, or damage to, patient- specific materials or our NurOwn ® stem cell therapy during storage at our facilities; ~~and~~ **and48** ~~*~~ ● loss or destruction of, or damage to, patient- specific materials or our NurOwn ® stem cell therapy stored at clinical and future commercial sites due to improper handling or holding by clinicians, hospitals or physicians. If we are unable to coordinate appropriately, we may encounter delays or additional costs in achieving our clinical and commercialization objectives, including in obtaining regulatory approvals of our stem cell therapies and supplying products, which could materially damage our business and financial position. ~~51We~~ **We** face competition in our efforts to develop cell therapies for ALS and other neurodegenerative diseases. We face competition in our efforts to develop cell therapies and other treatment or procedures to cure or slow the effects of ALS and other neurodegenerative diseases. Among our competitors are companies that are involved in the fetal- derived cell transplants or embryonic stem cell derived cell therapy and companies developing adult stem cells. Other companies are developing traditional chemical compounds, new biological drugs, cloned human proteins and other treatments, which are likely to impact the markets that we intend to target. Some of our competitors possess longer operating histories and greater financial, managerial, scientific and technical resources than we do, and some possess greater name recognition and established customer bases. Some also have significantly more experience in preclinical testing, human clinical trials, product manufacturing, the regulatory approval process and marketing and distribution than we do. The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us. There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies having greater financial resources and discovery technological capabilities, thus intensifying competition in these industries. This trend may also result in fewer potential collaborators or licensees for our stem cell therapies. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or collaborators as a result of such consolidation. There is a scarcity of experienced professionals in the field of cell therapy and we may not be able to retain key personnel or hire new key personnel needed to implement our business strategy and develop our products and businesses. If we are unable to retain or hire key personnel, we may be unable to continue to grow our business or to implement our business strategy, and our business may be materially and adversely affected. Given the specialized nature of cell therapy and the fact that it is a young field, there is an inherent scarcity of experienced personnel in the field. Our success depends on a significant extent to the continued services of certain highly qualified scientific and management personnel. We face competition for qualified personnel from numerous industry sources, and there can be no assurance that we will be able to attract and retain qualified personnel on acceptable terms. The loss of service of any of our key personnel could have a material adverse effect on our operations or financial condition. In the event of the loss of services of such personnel, no assurance can be given that we will be able to obtain the services of adequate replacement personnel. The future success of the Company also depends upon our ability to attract and retain additional qualified personnel (including medical, scientific, technical, commercial, business and administrative personnel) necessary to support our anticipated growth, develop our business, and maintain appropriate licensure, on acceptable terms. There can be no assurance that we will be successful in attracting or retaining personnel required by us to continue and grow our operations. The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees, as needed, could result in our inability to continue to grow our business or to implement our business strategy, or may have a material adverse effect on our business, financial condition and results of operations. Technological and medical developments or improvements in conventional therapies could render the use of stem cells and our services and planned products obsolete. The pharmaceutical industry is characterized by rapidly changing markets, technology, emerging industry standards and frequent introduction of new products. The introduction of new products embodying new technologies, including new manufacturing processes, and the emergence of new industry standards may render our technologies obsolete, less competitive or less marketable. Advances in other treatment methods or in disease prevention techniques could significantly reduce or entirely eliminate the need for our stem cell services, planned products and therapeutic efforts. Additionally, technological or medical developments may materially alter the commercial viability of our technology or services, and require us to incur significant costs to replace or modify equipment in which we have a substantial investment. In either event, we may experience a material adverse effect on our business, results of operations and financial condition. To date, approved conventional therapies have not shown significant clinical benefit as disease modifying therapies in the indications that we are currently working on. ~~52We~~ **49We** may expend our limited resources to pursue our NurOwn ® stem cell therapy or a specific indication for its use and fail to capitalize on stem cell therapies or indications that may be more profitable or for which there is a greater likelihood of success. Because we have

limited financial and managerial resources, we have focused development of our NurOwn ® stem cell therapy for use in patients with ALS, PMS and AD. As a result, we may forego or delay pursuit of opportunities with other stem cell therapies or for other indications that later prove to have greater commercial potential. Our resource allocation decisions also may cause us to fail to capitalize on a viable commercial treatment, a more viable indication or profitable market opportunities. We have based our research and development efforts on our NurOwn ® stem cell therapy. Notwithstanding our large investment to date and anticipated future expenditures in our NurOwn ® stem cell therapy, we have not yet developed, and may never successfully develop, any marketed treatments using this approach. As a result of pursuing the development of our NurOwn ® stem cell therapy, we may fail to develop stem cell therapies or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success. Our NurOwn ® stem cell therapy is based on a novel technology, which may raise development issues that we may not be able to resolve, regulatory issues that could delay or prevent approval or personnel issues that may keep us from being able to develop our treatments. Regulatory approval of stem cell therapies that utilize novel technology such as ours can be more expensive and take longer than for other treatments that are based on more well- known or more extensively studied technology. This may lengthen the regulatory review process, require us to perform additional studies, including clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these stem cell therapies or lead to significant post-approval limitations or restrictions. For example, the differentiated cell component of our NurOwn ® stem cell therapy is a complex biologic product that is manufactured from the patient' s own bone marrow that must be appropriately harvested, isolated, expanded and differentiated so that its identity, strength, quality, purity and potency may be characterized prior to release for treatment. No differentiated cell treatment for ALS has yet been approved for marketing by the FDA or any other regulatory agency. The novel nature of our NurOwn ® stem cell therapy also means that fewer people are trained in or experienced with treatments of this type, which may make it difficult to recruit, hire and retain capable personnel for the research, development and manufacturing positions that will be required to continue our development and commercialization efforts. We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws health information privacy and security laws, and other health care laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti- Kickback Statute, the federal civil and criminal False Claims Act and Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to: * the federal Anti-Kickback Statute, which prohibits, among other things, persons or **For more information** entities from knowingly and willfully soliciting , **see** receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties; * the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, 53among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to " **Business –** cause " the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a " whistleblower " to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery; * the anti- inducement law, which prohibits, among other **Other** things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary' s selection of a particular supplier of items or services reimbursable by a federal or state governmental program; * the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare **Healthcare Laws** benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and **Compliance** knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; * HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH and their respective

~~implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements~~ **Requirements** ~~on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information~~ . ~~HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non- U. S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; * The U. S. federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non- physician providers such as physician assistants and nurse practitioners; * federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; * federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and *~~ Many states in the United States have enacted laws that regulate the privacy and / or security of certain types of personal information. For example, in California **,** the California Consumer Privacy Act (the " CCPA "), ~~as amended by the California Privacy Rights Act (the " CPRA "), which went into effect on January 1, 2023,~~ created a ~~new~~ **comprehensive** privacy framework for covered businesses by creating an expanded definition of personal information, established new data privacy rights for consumers in the State of California, imposed special rules on the collection of consumer data from minors, and created a new and potentially ~~54severe~~ -- **severe** statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. **In addition, the California Privacy Rights Act (the " CPRA ") was passed in November 2020, and as of January 1, 2023, has imposed additional obligations on companies covered by the legislation.** The **CPRA significantly modified the** CCPA **, including by expanding consumers' rights with respect to sensitive personal information** and ~~the CPRA also~~ created a new state agency that is vested with authority to implement and enforce the CCPA ~~and the CPRA~~ . Although clinical trial data and protected health information subject to HIPAA are currently exempt from CCPA, we may be subject to the CCPA with respect to other personal information regarding California residents. **50The** ~~Additionally, some observers have noted that the~~ CCPA ~~and CPRA could~~ mark the beginning of a trend toward more stringent privacy legislation in the U. S., which could increase our potential liability and adversely affect our business. **Similar laws** ~~Already, in the United States, we~~ have ~~witnessed significant developments at~~ **been passed in numerous** ~~the~~ **other** ~~state~~ **states** ~~level~~ . **These enacted** ~~For example, on January 1, 2023, the Virginia Consumer~~ **consumer** ~~Data~~ **data** ~~Protection Act (the " CDPA ") became effective. Further, many additional U. S. state~~ privacy laws ~~will go into effect throughout 2023: the Colorado Privacy Act (the " CPA ") (July 1, 2023); the Connecticut Data Privacy Act (the " CTDPA ") (July 1, 2023); and the Utah Consumer Privacy Act (the " UCPA ") (December 31, 2023). The CDPA, CPA, CTDPA, and UCPA~~ are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data and limited obligations for entities regulated by HIPAA. ~~The~~ **These** ~~new~~ **comprehensive consumer privacy** laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. A number of other states have **also** proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. **There are also states that are specifically regulating health information. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data.** In addition ~~to~~ **,** ~~the~~ **other** ~~above, on November 20, 2020,~~ **states have proposed and / or passed legislation that regulates** the ~~Office~~ **privacy and / or security** of ~~Inspector General,~~ **certain specific types of information.** ~~or~~ **For** ~~OIG finalized further modifications to~~ **example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and** ~~the~~ **there is discussion in the U. S. Congress of a new comprehensive** federal ~~Anti- Kickback Statute~~ **data privacy law to which we may likely become subject, if enacted** . ~~Under~~ **The evolving compliance and operational requirements related to** ~~the~~ **these various state data privacy** ~~final rules, OIG added safe harbor protections under the Anti- Kickback Statute for certain coordinated care~~ and **security laws impose significant costs** ~~value- based arrangements among clinicians~~ , ~~providers~~ **such as costs related to organizational changes** , **implementing additional** ~~and others, yet removed safe harbor~~ protection **technologies, training employees and engaging**

consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management' s time and / ~~for -~~ or ~~price reductions~~ divert resources from ~~pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the~~ **other** ~~price reduction is required~~ **initiatives and projects. Any failure or perceived failure** by **us to comply with any applicable federal, state or foreign** ~~law~~ **laws and** ~~. The rule also creates a new safe harbor for price reductions~~ **regulations** ~~reflected at the point- of- sale~~ **relating to data privacy and security could result in damage to our reputation** , as well as **proceedings** ~~a safe harbor for -~~ **or litigation by governmental agencies or other third parties, including class action privacy litigation in** certain **jurisdictions** ~~fixed fee arrangements between pharmacy benefit managers and manufacturers. This rule (with exceptions) became effective January 19 , 2021. We continue~~ **which would subject us** to ~~evaluate what~~ **significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse** effect ~~, if any, these rules will have~~ on our business **, financial condition, results of operations and prospects** . Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U. S. states have adopted laws similar to the federal Anti- Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and / or the Pharmaceutical Research and Manufacturers of America' s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the GDPR in the EEA, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. ~~55Because~~ **51Because** of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers, some of whom receive share options as compensation for services provided, are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. It is uncertain to what extent the government, private health insurers and third- party payors will approve coverage or provide reimbursement for the therapies and products to which our services relate. Availability for such reimbursement may be further limited by an increasing uninsured population and reductions in Medicare and Medicaid funding in the United States. In the United States and markets in other countries, patients generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Our ability to successfully commercialize our human therapeutic products will depend significantly on our ability to obtain acceptable prices and the availability of reimbursement to the patient from third- party payors, such as government and private insurance plans. Although we have commenced initial discussions with such parties, pricing for our product, if approved, is yet to determined. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be covered and paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other payors. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA- approved products for a particular indication. A decision by a payor not to cover our gene therapies could reduce physician utilization of our products once approved, and have a material adverse effect on our sales, results of operations and financial condition. **For more information, see " Business – Third Party Payor Coverage and Reimbursement. "** There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about coverage and reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U. S. Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed

under Medicare. Private payors tend to follow the CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Factors payors consider in determining reimbursement are based on whether the product is: * ● a covered benefit under its health plan; * ● safe, effective and medically necessary; * ● appropriate for the specific patient; * ● cost- effective; and * ● neither experimental nor investigational. ~~These~~ **52These** third- party payors frequently require companies to provide predetermined discounts from list prices, and they are increasingly challenging the prices charged for pharmaceuticals and other medical products. Our human therapeutic products may not be considered cost- effective, and reimbursement to the patient may not be available or sufficient to allow us to sell our products on a competitive basis. ~~56Further~~ -- **Further** , as cost containment pressures are increasing in the health care industry, government and private payors adopt strategies designed to limit the amount of reimbursement paid to health care providers. Such cost containment measures may include: * ● Reducing reimbursement rates; * ● Challenging the prices charged for medical products and services; * ● Limiting services covered; * ● Decreasing utilization of services; * ● Negotiating prospective or discounted contract pricing; * ● Adopting capitation strategies; and * ● Seeking competitive bids. Similarly, the trend toward managed health care and bundled pricing for health care services in the United States could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our therapies. We may not be able to negotiate favorable reimbursement rates for our human therapeutic products. If we fail to obtain acceptable prices or an adequate level of reimbursement for our products, the sales of our products would be adversely affected or there may be no commercially viable market for our products. Unintended consequences of recently adopted health reform legislation in the U. S. may adversely affect our business. The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the U. S., comprehensive programs are under consideration that seek to, among other things, increase access to healthcare for the uninsured and control the escalation of healthcare expenditures within the economy. Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. **We cannot predict** ~~In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which, among other~~ -- **the initiatives** ~~things, subjected biologic products to potential competition by lower- cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs~~ that **may be adopted** ~~are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled~~ in ~~Medicaid~~ **the future. The continuing efforts of the government, insurance companies,** managed care organizations ~~, subjected manufacturers to new annual fees....., insurance companies, managed care organizations~~ and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: * ● the demand for our product candidates, if we obtain regulatory approval; * ● our ability to set a price that we believe is fair for our products; * ● our ability to generate revenue and achieve or maintain profitability; * ● the level of taxes that we are required to pay; and * ● the availability of capital. Any reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability. ~~We~~ **53We** expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures. **Moreover** ~~Appropriations Act (H.R.1865) , which repealed~~ **increasing efforts by governmental and third- party payors in** the ~~Cadillac tax,the~~ **United States and abroad to cap or reduce** ~~health~~ **healthcare** ~~insurance provider tax,~~ **costs may cause such organizations to limit both coverage** and the ~~medical device excise tax~~ **level of reimbursement for newly approved products and,as a result,they may not cover or provide adequate payment for our product candidates** . ~~It is impossible to determine whether similar taxes could be instated in the future.58Additionally,there~~ **There** has been increasing legislative and enforcement interest in the United States with respect to **specialty** drug pricing practices.Specifically,there ~~has~~ **have** been ~~heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products,which has resulted in~~ several **recent** U.S.Congressional inquiries and proposed and enacted federal and state legislation designed to,among other things,bring more transparency to drug pricing,reduce the cost of prescription drugs under Medicare, ~~and~~ review the relationship between pricing and manufacturer patient programs **,and reform government program reimbursement methodologies for drugs** . ~~At a federal 59Individual~~ -- **Individual** states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects. Ethical and other concerns surrounding the use of stem cell therapy may negatively impact the public perception of our stem cell services, thereby suppressing demand for our services. Although our stem cell business pertains to adult stem cells only and does not involve the more controversial use of embryonic stem cells, the use of adult human stem cells for therapy could give rise to similar ethical, legal and social issues as those associated with

embryonic stem cells, which could adversely affect its acceptance by consumers and medical practitioners. Additionally, it is possible that our business could be negatively impacted by any stigma associated with the use of embryonic stem cells if the public fails to appreciate the distinction between adult and embryonic stem cells. Delays in achieving public acceptance may materially and adversely affect the results of our operations and profitability. We may be subject to significant product liability claims and litigation which could adversely affect our future earnings and financial condition. Our business exposes us to potential product liability risks inherent in the testing, processing and marketing of stem cell therapy products. Specifically, the conduct of clinical trials in humans involves the potential risk that the use of our stem cell therapy products will result in adverse effects. Such liability claims may be expensive to defend and result in large judgments against us. We currently maintain liability insurance for our clinical trials; however, such liability insurance may not be adequate to fully cover any liabilities that arise from clinical trials of our stem cell therapy products. We also maintain errors and omissions, directors and officers, workers' compensation and other insurance appropriate to our business activities. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our own limited resources, which could have a material adverse effect on our financial condition, results of operations and business. Additionally, liability or alleged liability could harm our business by diverting the attention and resources of our management and damaging our reputation and that of our subsidiaries. **54Our business could be adversely affected by the effects of health epidemics, including any ongoing public health crises, in regions where we operate. Public health crises such as pandemics or similar outbreaks could adversely impact our business. Although the U. S. government has declared an end to the Public Health Emergency related to COVID- 19, there may be lingering effects of the COVID- 19 pandemic on our business. The COVID- 19 may continue to impact the United States, Europe and Israel, where we conduct our operations, as well as our clinical trials for NurOwn ®. The full extent to which the COVID 19 pandemic will continue to directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted at this time, including new information that may emerge concerning COVID 19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. The adverse impact of public health crises such as pandemics or similar outbreaks in the countries and regions where we have concentrations of potential clinical trial sites or other business operations and where several of our third- party suppliers and contractors are located could adversely affect our business, including by causing significant disruption in the operations of third parties upon whom we rely. The COVID- 19 endemic presented a substantial public health and economic challenge around the world and affected employees, patients, communities and business operations, as well as the U. S. economy and financial markets.** Political, economic and military instability in Israel may impede our ability to execute our plan of operations. Our principal operations and the research and development facilities of the scientific team funded by us under the Second Ramot Agreement are located in Israel. Accordingly, political, economic and military conditions in Israel may affect our business **and operations are directly affected by economic, political, geopolitical and military conditions in Israel** . Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its ~~Arab neighbors~~ **neighboring countries and terrorist organizations active in the region** . Acts of random terrorism periodically occur which could affect our operations or personnel. **The conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel.** Ongoing or revived hostilities or other factors related to Israel could harm our operations and research and development process and could impede our ability to execute our plan of operations **. In October 2023, Hamas terrorists infiltrated Israel' s southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel' s border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel' s security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict. Although we currently do not expect the ongoing conflict to affect our customers, manufacturing, research and development, supply chain, commercialization activities and current clinical studies, there can be no assurances that further unforeseen events will not have a material adverse effect on us or our operations in the future. The Israel Defense Force (the " IDF "), the national military of Israel, is a conscripted military service, subject to certain exceptions. Since October 7, 2023, the IDF has called up more than 350, 000 of its reserve forces to serve. It is possible that there will be further military reserve duty call- ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third- party outsourcing, for example, may have unintended negative effects and adversely impact our results of operations, liquidity or cash flows. It is currently not possible to predict the duration or severity of the ongoing conflict or its efforts on ours business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations, interrupt our sources and availability of supply and hamper our ability to raise additional funds or sell our securities, among others** . In addition, Israeli- based companies and companies doing business with Israel have been the subject of an economic boycott by members of the Arab League and certain other predominantly Muslim countries since Israel' s establishment. Although Israel has entered into various agreements with certain Arab countries and the Palestinian Authority, and various declarations have been signed in connection with efforts to resolve some of the economic and political problems in the Middle East, we cannot predict whether or in what manner ~~these~~ **55these** problems will be resolved. Wars and acts of terrorism have resulted in damage to the Israeli economy, including reducing the level of foreign and local investment. The Israeli government is currently pursuing extensive reforms to Israel' s judicial system. In response to the foregoing developments, many individuals,

organizations and institutions, both within and outside of Israel, have voiced concerns that the proposed reforms may negatively impact the business environment in Israel including due to increased currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in securities markets, and other changes in macroeconomic conditions. To the extent that any of these negative developments do occur, they may have an adverse effect on our business, our results of operations and our ability to raise additional funds, if deemed necessary by our management and board of directors. **If our** ~~60Furthermore, certain of our~~ **or our vendors' security measures** ~~officers and employees may be obligated to perform annual reserve duty in the Israel Defense Forces and~~ are **breached** ~~subject to being called up for~~ **or** ~~active military duty at any time~~ **unauthorized access to individually identifiable health information or other personally identifiable information is otherwise obtained, our reputation may be harmed, and we may incur significant liabilities** . ~~Israeli citizens~~ **Unauthorized access to, or cybersecurity incidents relating to, our or our vendors' systems and databases could result in unauthorized access to data and information loss, compromise, or corruption of such data and information. Cybersecurity incidents have been increasing in sophistication and frequency and can include third parties gaining access to employee or customer data using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks, ransomware, social engineering, and other deliberate attacks and attempts to gain unauthorized access. Because the techniques used by threat actors** who ~~have served in the army~~ may **attempt** ~~be subject~~ to **penetrate** ~~an~~ **and sabotage** ~~obligation to perform reserve duty until they are between 40 and 49 years old, depending upon the nature of their military service. Man- Made Problems Such as Computer Viruses or~~ **our** ~~Terrorism May Disrupt Our Operations and Harm Our Operating ResultsDespite our implementation of~~ network security ~~measures our~~ **or our website change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques. In the event of a cybersecurity incident, we could suffer loss of business,** ~~servers~~ **severe** ~~are vulnerable to computer viruses~~ **reputational damage adversely affecting investor confidence** , **regulatory investigations** ~~break- ins,~~ and ~~similar disruptions~~ **orders, litigation, indemnity obligations, damages for contract breach, penalties for violation of applicable laws or regulations, significant costs for remediation and other liabilities. For example, the loss of preclinical study or clinical trial data** from **completed** ~~unauthorized tampering with our~~ **or** ~~computer systems. Any such event~~ **future preclinical studies or clinical trials** could ~~have a material adverse effect on our business, operating results~~ **result in delays in** ~~, and financial condition. Efforts to limit the ability of malicious third parties to disrupt the operations of the internet or~~ **our regulatory approval** ~~undermine our own security~~ efforts ~~may meet with resistance. In addition, the continued threat of terrorism~~ and **significantly increase** ~~heightened security and military action in response to this threat, or~~ **our costs** ~~any future acts of terrorism, may cause further disruptions~~ to **recover** ~~the economies of the United States, Israel and other countries and create further uncertainties or otherwise materially harm our~~ **or reproduce the data** ~~business, operating results, and financial condition. Likewise, events such as widespread blackouts could have similar negative impacts~~ . To the extent that **any disruption or cybersecurity incident were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. We have incurred and expect to incur significant expenses to try to prevent cybersecurity incidents, including costs related to deploying additional personnel and protection technologies, training employees, and engaging third- party solution providers and consultants. Although we expend resources in an effort to protect our customer data against potential theft and cybersecurity incidents, we have been subject to attempted cyber- attacks in the past, and** such ~~disruptions~~ **measures cannot provide absolute security. Moreover, as we outsource more of** ~~or~~ **our** ~~uncertainties~~ **information systems to vendors and rely more on cloud- based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems. Despite our efforts, we remain at risk for cybersecurity incidents, including, without limitation, incidents that may occur as a** result **of third- party action** ~~in delays or access to data or personal information~~ , ~~our~~ **or** ~~business~~ **employee** , ~~operating results,~~ **vendor or contractor error or malfeasance** and **other causes. If, in the future, we experience a material cybersecurity incident, we would likely experience harm to our reputation,** financial **performance,** ~~condition could be materially~~ and ~~adversely affected~~ **customer and vendor relationships, and the possibility of litigation or regulatory investigations or actions by state and federal governmental authorities and non- U** . **S. authorities. Additionally, actual, potential, perceived or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third- party experts and consultants.** ~~Changes~~ **56Changes** in Tax Law may Adversely Affect our Business and Financial ConditionThe laws and rules dealing with U. S. federal, state and local income taxation are routinely being reviewed and modified by governmental bodies, officials and regulatory agencies, including the Internal Revenue Service and the U. S. Treasury Department. Since inception, many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, that could result in an increase in our or our stockholders' tax liability. Risks Related to Government RegulationWe are subject to a strict regulatory environment. If we fail to obtain and maintain required regulatory approvals for our potential cell therapy products, our ability to commercialize our potential cell therapy products will be severely limited. None of our stem cell therapies have received regulatory approval for commercial sale. Numerous statutes and regulations govern human testing and the manufacture and sale of human therapeutic products in the United States and other countries where we intend to market our products. Such legislation and regulation bears upon, among other things, the approval of protocols and human testing, the approval of manufacturing facilities, testing procedures and controlled research, review and approval of manufacturing, preclinical and clinical data prior to marketing approval including adherence to cGMP during production and storage as well as regulation of marketing activities including advertising and labeling. The completion of the clinical testing of our stem cell therapies and the obtaining of required approvals are expected to require the expenditure of substantial resources. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that

could delay or prevent regulatory approval and / or commercialization of our stem cell therapies, including the following: ● The FDA or similar foreign regulatory authorities may find that our stem cell therapies are not sufficiently safe or effective or may find our processes or facilities unsatisfactory; ● Officials at the Israeli MoH, the FDA or similar foreign regulatory authorities may interpret data from preclinical studies and clinical trials differently than we do; ● Our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the Israeli MoH, the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and / or clinical trials or to abandon one or more of our development programs; ● The Israeli MoH, the FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations; ~~61~~ ● There may be delays or failure in obtaining approval of our clinical trial protocols from the Israeli MoH, the FDA or other regulatory authorities or obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites; ● We, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects; and ● Enrollment in our clinical trials for our stem cell therapies may occur more slowly than we anticipate, or we may experience high drop- out rates of subjects in our clinical trials, resulting in significant delays. Investors should be aware of the risks, problems, delays, expenses and difficulties which may be encountered by us in light of the extensive regulatory environment in which our business operates. In particular, our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval may be delayed or denied by the Israeli MoH or the FDA. ~~On~~ **57On** February 22, 2021, we announced high- level FDA feedback on NurOwn ® ALS Clinical Development Program. The FDA concluded from their initial review that the current level of clinical data does not provide the threshold of substantial evidence that FDA is seeking to support a BLA. On March 2, 2021, the FDA issued a public statement that the data from the Phase 3 ALS study do not support the proposed clinical benefit of NurOwn ® and that the FDA would continue to provide advice to us on our development program. On August 15, 2022, we announced our decision to submit a BLA to the FDA for NurOwn ® for the treatment of ALS. The BLA was filed on September 9, 2022. On November 10, 2022, we announced that we had received a RTF letter from the FDA regarding our BLA for NurOwn ® for the treatment of ALS. The FDA informed us that the BLA is not sufficiently complete to enable a substantive review and that the FDA would therefore not file the BLA. The RTF letter contained a list of topics the FDA provided to BrainStorm as rationale for the BLA file being not sufficiently complete to enable a substantive review. According to the FDA, these reasons included one item related to the trial not meeting the standard for substantial evidence of effectiveness and ~~Chemistry, Manufacturing and Controls (“~~ CMC ~~”)~~ related items. The FDA indicated that we may request a Type A meeting to discuss the content of the RTF letter. On December 12, 2022, we announced the submission of a Type A meeting request with **the** FDA to discuss the contents of the RTF letter previously issued by the FDA regarding our BLA for NurOwn ® for the treatment of ALS. On December 27, 2022, we announced that the FDA granted a Type A meeting to discuss the contents of the RTF letter previously issued regarding our BLA for NurOwn ® for the treatment of ALS. The Type A Meeting was held on January 11, 2023. The perspective shared by the FDA review team reflected what was in the previously issued RTF letter. Conversations on the best pathway to resolve the outstanding questions that ~~remained~~ continued following the Type A meeting. During these discussions, we were presented with multiple options to return the BLA to regulatory review, which included the regulatory procedure to File over Protest. These discussions resulted in our requesting the FDA to file our BLA over Protest, as this was the regulatory procedure that would allow us to reach an ADCOM in the shortest amount of time. We notified the FDA on February 6, 2023 of our decision to request the FDA to file the NurOwn **®** BLA for ALS over protest. We received the FDA Type A meeting minutes on February 9, 2023. We submitted an amendment to our BLA on March 7, 2023, in which we responded to the majority of the items included in the RTF letter. Written feedback was received on March 22, 2023 from the FDA project manager associated with the BLA confirming the FDA’ s decision to grant an ADCOM for the NurOwn **®** BLA for ALS ~~. The BLA for NurOwn to treat ALS is currently under active review by the FDA~~ . The approval process is lengthy and difficult and the FDA, Israeli MoH, or other regulatory authorities may refuse to approve a BLA or equivalent marketing application if the applicable regulatory criteria are not satisfied. Generally, the FDA does not favor the File over Protest procedure. There are also certain consequences of filing an application over Protest. For example, such an application would not be eligible for certain FDA communications over the course of the review cycle. When an application is filed with the FDA over Protest, the FDA generally will not review amendments to the application during any review cycle and will not issue information requests to the applicant during the agency’ s review. When an application is Filed over Protest, the performance goals implemented by the FDA under PDUFA do not apply to any resubmission of the application following an FDA complete response action, and any such resubmission is reviewed as available resources permit. **If convened,** ~~The FDA may have difficulties scheduling~~ an advisory committee ~~meeting in a timely manner. Further, an advisory committee~~ may recommend against approval of ~~our~~ **a** BLA or may recommend that the FDA require, as a condition of approval, additional preclinical ~~62studies~~ -- **studies** , clinical trials or investigations, limitations on approved labeling or distribution and use restrictions. Even if an advisory committee ~~, if convened,~~ makes a favorable recommendation, the FDA may still not approve ~~our~~ **the** product candidate **. On March 27, 2023, we announced that the FDA will hold an ADCOM to discuss the company’ s BLA for NurOwn ® for the treatment of ALS. On June 6, 2023, we announced that the advisory committee meeting has been scheduled for September 27, 2023. On September 27, 2023, we announced that the Advisory Committee voted, with 17 voting no, one voting yes, and one abstention, that NurOwn ® did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS. On November 20, 2023, we announced that the FDA granted the company a meeting to discuss the regulatory path forward for NurOwn ® in ALS. The meeting took place on December 6, 2023. On December 7, 2023, we announced the completion of a productive meeting with the FDA to discuss NurOwn ®. The primary objective of the meeting was to discuss plans for a Special Protocol Assessment (SPA) with FDA on the overall protocol design for a planned Phase 3b registrational trial for NurOwn ®. The ultimate goal of the SPA is to**

secure the FDA' s agreement that critical elements of the overall protocol design (e. g., entry criteria, endpoints, planned analyses) are adequate and acceptable for a study intended to support a future marketing application. On February 23, 2024, we announced that we submitted the SPA request to the FDA for the planned Phase 3b clinical trial of NurOwn ® for the treatment of ALS . Even if a stem cell therapy is approved by the Israeli MoH, the FDA or any other regulatory authority, we may not obtain approval for an indication whose market is large enough to recoup our investment in that stem cell therapy. We may never obtain the required regulatory approvals for any of our stem cell therapies. Later ~~discovery~~ **58discovery** of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Additional time may be required to obtain regulatory approval for our product candidates because they are combination products. NurOwn ® is being developed, and future product candidates may be developed, as combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug / biologic components. Medical products containing a combination of new drugs, biological products or medical devices may be regulated as " combination products. " In the United States, a combination product generally is defined as a product comprised of components from two or more regulatory categories (e. g., drug / device, device / biologic, drug / biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate premarket review of combination products, the FDA designates one of its centers to have primary jurisdiction for the premarket review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug or biologic and device is sought under a single application, there could be delays in the approval process due to the increased complexity of the review process **. The FDA' s agreement to any Special Protocol Assessment with respect to the study design of our planned Phase 3b clinical trial of NurOwn ® for the treatment of ALS does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a successful review or approval process. We have submitted a SPA request to the FDA for a Phase 3b clinical trial of NurOwn ® for the treatment of ALS. The FDA' s SPA process is designed to facilitate the FDA' s review and approval of drugs and biologics by allowing the FDA to evaluate the proposed design and size of certain clinical or animal studies, including clinical trials that are intended to form the primary basis for determining a product candidate' s efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor' s questions regarding protocol design and scientific and regulatory requirements. The FDA aims to complete SPA reviews within 45 days of receipt of the request. The FDA ultimately assesses whether specific elements of the protocol design of the trial, such as entry criteria, dose selection, endpoints and / or planned analyses, are acceptable to support regulatory approval of the product with respect to the effectiveness of the indication studied. All exchanges between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA. Although the FDA may agree to an SPA, an SPA agreement does not guarantee approval of a product. Even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol. Generally, such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. Moreover, if the FDA revokes or alters any agreement reached under a SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval of NurOwn ® for the treatment of ALS** . Even though we have obtained Fast Track designation for NurOwn ® for the treatment of ALS in the United States, Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. If a biologic is intended for the treatment of a serious or life- threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation for a particular indication. The FDA has granted Fast Track designation for NurOwn ® for the treatment of ALS and we may seek Fast Track designation for certain other of our current or future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. If granted, Fast Track designation makes a product eligible for more frequent interactions with **the** FDA to discuss the ~~development~~ **59development** plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Marketing applications of products candidates with Fast Track designation may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide any assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time. Even though we have obtained Orphan Drug Designation for NurOwn **®** for ~~,~~ the treatment of ALS ~~,~~ in

the United States and EU, and we may apply for Orphan Drug Designation for other product candidates, we may not be able to obtain such designations or maintain the benefits associated with orphan drug status, including orphan drug marketing exclusivity. Regulatory authorities in some jurisdictions, including the United States and **EU** ~~European Union~~, may designate drugs or biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States, or a patient population of 200, 000 or more in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In order to obtain Orphan Drug Designation, the request must be made before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user- fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. ~~63If~~ **If** a product that has Orphan Drug Designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, to market the biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or orphan drug exclusivity can be overcome if a subsequent applicant demonstrates clinical superiority over our product. In the **EU** ~~European Union~~, the Committee for Orphan Medicinal Products of the EMA grants orphan designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, which either affects not more than five in 10, 000 persons in the **EU** ~~European Union~~, or products intended for the diagnosis, prevention or treatment of a life- threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that the medicine would generate sufficient return to justify the necessary investment in its development. In each case, there must be no satisfactory method of diagnosis, prevention, or treatment which is authorized for marketing in the **EU** ~~European Union~~, or, if a method exists, the product would be of significant benefit to those affected by the condition. We have obtained from the FDA and EMA Orphan Drug Designations for NurOwn ® for the treatment of ALS. We may seek Orphan Drug Designation for other product candidates. Even if we obtain Orphan Drug Designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective, if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products. In addition, although we may seek Orphan Drug Designation for other product candidates, we may never receive such designations. Any failure to obtain, maintain or otherwise recognize the benefits of orphan drug designation for our products or product candidates could have a material adverse effect on our prospects. On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017 ~~, or~~ **(“** FDARA **”)** . FDARA, among other things, codified the FDA’ s pre- existing regulatory interpretation to require that a sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The legislation ~~reverses~~ **60reverses** prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies’ operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. ~~64Even~~ -- **Even** if regulatory approvals are obtained for our stem cell therapies, we will be subject to ongoing government regulation. If we or one or more of our partners or collaborators fail to comply with applicable current and future laws and government regulations, our business and financial results could be adversely affected. Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse

event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post- marketing information. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and product listing, as well as continued compliance by us and / or any future CMOs ~~and contract research organizations (“~~ CROs ~~”)~~ for any post- approval clinical trials that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS, impose significant restrictions on a product’ s indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. In addition, manufacturers of cell therapies and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, GCP, cGTP, and other regulations. For certain commercial prescription and biologic products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may: ● issue warning letters or untitled letters; ● mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products; **61** ● require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; ● seek an injunction or impose civil or criminal penalties or monetary fines; ● suspend, withdraw or modify regulatory approval; ● suspend or modify any ongoing clinical trials; ● refuse to approve pending applications or supplements to applications filed by us; ● suspend or impose restrictions on operations, including costly new manufacturing requirements; or ● seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall. The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U. S. Federal Trade Commission, the Department of Justice (“ DOJ ”), the Office of Inspector General (“ OIG ”) of the ~~U. S. Department of Health and Human Services (“~~ HHS ~~”)~~, state attorneys general, members of the U. S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off- label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the ~~65FDA~~ -- **FDA** or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties. The FDA and other regulatory authorities’ policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any current or future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained. Non- compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties. We are subject to environmental, health and safety laws. We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and humans, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts. We are subject to significant regulation with respect to manufacturing of our NurOwn ® stem cell therapy. All entities involved in the preparation of a therapeutic biological for clinical trials or commercial sale are subject to extensive regulation. Our NurOwn ® stem cell therapy must be manufactured in accordance with cGMP and cGTP before it can be used in our clinical trials or approved for commercial sale. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational stem cell therapies and treatments, including treatment component characterization and process validation, approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party suppliers must pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our NurOwn ® stem cell therapy. If any inspection or audit of our manufacturing facilities ~~identifies~~ **62identifies** a failure to comply with applicable regulations, or if a violation of applicable regulations occurs independent of an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and / or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed on us or third parties with whom we contract could materially harm our business. For certain commercial prescription biologic products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying

the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. Our long- term business plan is to develop our NurOwn ® stem cell therapy for the treatment of neurodegenerative diseases, such as ALS, PMS and AD. Even if we successfully develop our NurOwn ® stem cell therapy for use in one indication, we may not be successful in our efforts to identify or discover additional indications for it. Clinical programs to develop new indications for our NurOwn ® stem cell therapy will require substantial technical, financial and human resources. These development programs may initially show promise in identifying potential treatment indications, yet fail to obtain regulatory approval for commercial sale. If we do not accurately evaluate the commercial potential or target market for our NurOwn ® stem cell therapy, we may relinquish valuable rights to that treatment through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. ~~66Risks~~ -- **Risks** Related to Our Intellectual PropertyIf we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop, and our technology may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business; we may in the future also license or purchase patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed. If the scope of the patent protection we or our potential licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot assure you that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed (21 years if first filed as a provisional application). Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if they are unchallenged, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non- infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and / or a device that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product ~~candidates~~ **63candidates** is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. We currently own or have exclusively in- licensed all of our patents or patent applications. Similar risks would apply to any patents or patent applications that we may own and those which we may license in the future. In many cases, in- licensed intellectual property is at greater risk, as we may not have access to all information or to prosecution and other aspects of the acquisition, maintenance and enforcement of the in- licensed intellectual property. Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. No consistent policy governing the scope of claims allowable in the fields of antibodies and radiopharmaceuticals has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license. ~~67The~~ -- **The** patent prosecution process is complex, expensive, time- consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, corporate collaborators, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not until issuance as a patent. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications. The issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Further, the scope of the invention claimed in a

patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even where patent applications we currently own, license, or that we may license in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade our patent rights by developing alternative technologies or products in a non- infringing manner. The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third- party pre- issuance submission of prior art or opposition, derivation, revocation, re-examination, post- grant and inter partes review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the ~~U. S. Patent and Trademark Office, or the~~ USPTO ~~,~~ or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third- party patent rights. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in- licensed patents and patent applications are, and may in the future be, co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co- owners of our owned and in- licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. ~~Part~~ **64Part** of our business in the foreseeable future will be based on technology licensed from Ramot and if this license were to be terminated upon failure to make required royalty payments in the future, we would need to change our business strategy and we may be forced to cease our operations. Agreements we and our Israeli Subsidiary have with Ramot impose on us royalty payment obligations. If we fail to comply with these obligations, Ramot may have the right to terminate the license under certain circumstances. If Ramot elects to terminate our license, we would need to change our business strategy and we may be forced to cease our operations. We currently do not owe Ramot any overdue payments. Royalties are due upon commencement of revenues by the Company. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensors may have the right to terminate the licenses, in which event we would not be able to develop or market the products covered by such licensed intellectual property. ~~68These~~ -- **These** agreements impose numerous obligations, such as diligence and payment obligations. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. These licenses do and future licenses may include provisions that impose obligations and restrictions on us. This could delay or otherwise negatively impact a transaction that we may wish to enter into. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including disputes concerning: ● the scope of rights granted under the license agreement and other interpretation- related issues; ● whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; ● our right to sublicense patent and other rights to third parties under collaborative development relationships; ● our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and ● the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer. If Ramot is unable to obtain patents on the patent applications and technology licensed to our Israeli Subsidiary or if patents are obtained but do not provide meaningful protection, we may not be able to successfully market our proposed products. We rely upon the patent applications filed by Ramot, the technology licensing company of Tel Aviv University, and the license granted to us by Ramot, all in accordance with the Second Ramot Agreement dated as of July 26, 2007. We further agreed under the Second Ramot Agreement that Ramot, in consultation with us, is responsible for obtaining patent protection for technology owned by Ramot and licensed to us. No assurance can be given that the scope of any patent protection granted will exclude competitors or provide us with competitive advantages, that any of the patents that may be issued to us will be held valid if subsequently challenged, or that other parties will not claim rights to or ownership of our patents or other proprietary rights that we hold license to. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or products or design around any patents that have been or may be issued to us or any future licensors. Since patent applications in the United States and in Europe are not disclosed until applications are published, there can be no assurance that others did not first file applications for products covered by our pending patent applications, nor can we be certain that we will not infringe any

patents that may be issued to others. Also, we have abandoned our rights to certain patents of Ramot in certain countries in connection with the Letter Agreement by and ~~between~~ **65between** us and Ramot dated December 24, 2009, which may limit our ability to fully market our proposed products. All granted patents related to NurOwn ® (MSC- NTF cells) manufacturing process are fully assigned to or owned by BrainStorm Cell Therapeutics Ltd. We also rely upon unpatented proprietary technology, know- how and trade secrets and seek to protect them through confidentiality agreements with employees, consultants and advisors. If these confidentiality agreements are breached, we may not have adequate remedies for the breach. In addition, others may independently develop or otherwise acquire substantially the same proprietary technology as our technology and trade secrets. ~~69We~~ **We** may be unable to protect our intellectual property from infringement by third parties. Despite our efforts to protect our intellectual property, third parties may infringe or misappropriate our intellectual property. Our competitors may also independently develop similar technology, duplicate our processes or services or design around our intellectual property rights. We may have to litigate to enforce and protect our intellectual property rights to determine their scope, validity or enforceability. Intellectual property litigation is costly, time- consuming, diverts the attention of management and technical personnel and could result in substantial uncertainty regarding our future viability. The loss of intellectual property protection or the inability to secure or enforce intellectual property protection would limit our ability to develop or market our services in the future. This would also likely have an adverse effect on the revenues generated by any sale or license of such intellectual property. Furthermore, any public announcements related to such litigation or regulatory proceedings could adversely affect the price of our Common Stock. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time- consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own. The intellectual property landscape around our product candidates is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Third- party claims of intellectual property infringement may prevent or delay our product discovery and development efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving the infringement of patents and other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights and who allege that our product candidates, uses and / or other proprietary technologies infringe their intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk that our product candidates may give rise to claims of infringement of the patent rights of others increases. Moreover, it is not always clear to industry participants, including us, which patents exist which may be found to cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications currently pending in our fields, there may be a risk that third parties may allege they have patent rights which are infringed by our product candidates, technologies or methods. If a third party alleges that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: ● infringement and other intellectual property misappropriation which, regardless of merit, may be expensive and time- consuming to litigate and may divert our management' s attention from our core business; ● substantial damages for infringement or misappropriation, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third- party' s rights, and, if the court finds we have willfully infringed intellectual property rights, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; **66** ● an injunction prohibiting us from manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party agrees to license its patent rights to us; ● even if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and / or grant cross- licenses to intellectual property rights protecting our products; and ~~70~~ ● we may be forced to try to redesign our product candidates or processes so they do not infringe third- party intellectual property rights, an undertaking which may not be possible or which may require substantial monetary expenditures and time. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If any of our product candidates are approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we may believe that patent claims or other intellectual property rights of a third party would not have a materially adverse effect on the commercialization of our product candidates, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is " clear and convincing, " a heightened standard of proof. There may be issued third- party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product

candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that may be infringed by our product candidates. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third- party patents, held now or obtained in the future by a third party, were found by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product or methods use of the product, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover any aspect of our formulations, any combination therapies or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. ~~71We~~ **67We** may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to take legal action to enforce our patents or our licensors' patents against such infringing activity. Such enforcement proceedings against infringers can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the compositions or activities in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense against these assertions, non-infringement, invalidity or unenforceability regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Post- grant proceedings provoked by third parties or brought by the USPTO may be brought to determine the validity or priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or post- grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as those within the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares. Issued patents covering our products and product candidates could be found invalid or unenforceable if challenged in court or the USPTO. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are various grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, inter partes review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, or if we are otherwise

unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. ~~72Obtaining~~ **68Obtaining** and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Some of our pending patent applications may not be allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that cause withdrawal of the allowance of a patent application. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the applicant may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will issue the application in view of the new material. Further, periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign countries may require the payment of maintenance fees or patent annuities during the lifetime of a patent application and / or any subsequent patent that issues from the application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application. Such noncompliance can result in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. Such an event could have a material adverse effect on our business. Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other drug and biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the drug and biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the United States has passed wide- ranging patent reform legislation under the AIA. Moreover, recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights. Our European patents and patent applications could be challenged in the recently created Unified Patent Court (UPC) for the European Union, that is expected to be fully ratified in 2023. We may decide to opt out our European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Under the UPC, a granted European patent would be valid and enforceable in numerous European countries. A successful invalidity challenge to a European patent under the UPC would result in loss of patent protection in those European countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European countries, rather than in each validated European country separately as such patents always have been adjudicated. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. ~~We~~ **69We** have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world. ~~73Certain~~ -- **Certain** of our key patent families have been filed in the United States; however, we have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue patent coverage of our product candidates in certain countries outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. The breadth and strength of our patents issued in foreign jurisdictions or regions may not be the same as the corresponding patents issued in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to certain territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protections,

particularly those relating to drug and biopharmaceutical products. This difficulty with enforcing patents could make it difficult for us to stop the infringement of our patents or marketing of competing products otherwise generally in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. As a result of our reliance on consultants, we may not be able to protect the confidentiality of our technology, which, if disseminated, could negatively impact our plan of operations. We currently have relationships with academic and industry consultants and subcontractors who are not directly employed by us, and we may enter into additional relationships of such nature in the future. We have limited control over the activities of these consultants and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, in connection with every relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results of operations. To the extent that our scientific consultants develop inventions or processes independently that may be applicable to our proposed products, disputes may arise as to the ownership of the proprietary rights to such information, we may expend significant resources in such disputes and we may not win those disputes. We received grants from the Israel Innovation Authority, or IIA, we are subject to on- going restrictions. We have received royalty- bearing grants from the IIA, for research and development programs that meet specified criteria. The terms of the IIA' s grants may limit various technology transfer know- how developed under an approved research and development program outside of Israel. ~~74We~~ **70We** may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. Many of our employees were previously employed at other biotechnology companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, financial condition and results of operations. If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Hatch- Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply for a patent extension within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we believe we are entitled to, our competitors may obtain approval of competing products sooner than we would expect, and our business, financial condition, results of operations, and prospects could be materially harmed. Risks related to our Common **StockIf we fail to regain compliance with the continued listing requirements of Nasdaq, our Common** ~~StockThe~~ **Stock may be delisted and the price and liquidity of our common stock may be negatively impacted. On November 1, 2023, we received a letter from the listing qualifications department staff (the " Staff ") of Nasdaq Stock Market (" Nasdaq ") indicating that we are not in compliance with the $ 1. 00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550 (a) (2) for continued listing on The Nasdaq Capital Market (the " Bid Price Requirement "). In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we have an initial compliance period of 180 calendar days from the date of the letter, or until April 29, 2024, to regain compliance with respect to the Bid Price Requirement. To regain compliance with the Bid Price Requirement, the closing bid price of our common stock must meet or exceed $ 1. 00 per share for a minimum of ten consecutive business days during the initial compliance period. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A) (ii), we may be eligible for an additional 180- day compliance period to demonstrate compliance with the Bid Price Requirement, subject to certain conditions. On November 6, 2023, we received a letter from the Staff notifying us that from September 25, 2023 to November 3, 2023, our Market Value of Listed Securities (" MVLS ") was below the minimum of $ 35 million for continued listing on The Nasdaq Capital Market pursuant to Nasdaq listing Rule 5550 (b) (2) (the " MVLS Requirement "). In accordance with Nasdaq Listing Rule 5810 (c) (3) (C), we have a compliance period of 180 calendar days from receipt of this letter, or until May 6, 2024, to regain compliance with respect to the MVLS Requirement. To regain compliance with the MVLS Requirement, our MVLS must close at $ 35 million or more for a minimum of ten consecutive business days during the compliance period. These letters had no immediate effect on the**

listing of the Common Stock on the Nasdaq Capital Market, and the Common Stock will continue to trade on The Nasdaq Capital Market under the symbol " BCLI. " However, if we do not regain compliance with the relevant listing requirement during the applicable compliance period, Nasdaq will notify us in writing of its determination to delist the Common Stock, at which point we would have an opportunity to appeal the delisting determination. However, there can be no assurance that, if we receive a delisting notice from the Staff and appeals the delisting determination, such appeal would be successful. 71We intend to actively monitor the closing bid price of the Common Stock and MVLS and will take all reasonable measures available to us to regain compliance with the Bid Price Requirement and the MVLS Requirement. There can be no assurance that we will be able to regain compliance with these listing requirements or otherwise maintain compliance with any other listing requirements. Delisting from the Nasdaq market could make trading the Common Stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of the Common Stock, the sale or purchase of the Common Stock would likely be made more difficult and the trading volume and liquidity of the Common Stock could decline. Delisting from Nasdaq could also result in negative publicity, could also make it more difficult for us to raise additional capital through alternative financing sources on terms acceptable to us, or at all, and may result in potential loss of confidence by investors, employees, and could result in fewer business development opportunities. We cannot assure you that the Common Stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over- the counter quotation system. We are and could be further subject to securities class action litigation and other types of stockholder litigation. The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. For example, in November 2023, a purported stockholder filed a lawsuit against us and certain of our officers captioned Sporn v. Brainstorm Cell Therapeutics, Inc. et al. in the U. S. District Court for the Southern District of New York, and in February 2024, two derivative actions were filed in the same court (see " Item 3. Legal Proceedings " for a more detailed description of these matters). We could also be subject to other types of litigation, which may involve claims of breach of fiduciary duties by our directors or officers for misuse / mismanagement of company assets / resources or conflicts of interest. Any such litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results, or financial condition. The price and trading volume of our stock is expected to be volatile. The market price and trading volume of our Common Stock has fluctuated significantly over time, and is likely to continue to be highly volatile. To date, the trading volume and price of our stock has seen significant fluctuations. We expect such fluctuations could occur in the future. Investors should be aware of the risks of trading in our Common Stock due to such volatility. Your percentage ownership will be diluted by future issuances of our securities. In order to meet our financing needs, we may issue additional significant amounts of our Common Stock and warrants to purchase shares of our Common Stock. The precise terms of any future financings will be determined by us and potential investors and such future financings may also significantly dilute your percentage ownership in the Company. ~~75ACCBT --~~ **ACCBT** holds equity participation rights and other rights that could affect our ability to raise funds. Pursuant to the Subscription Agreement with ACCBT Corp. (" ACCBT "), a company under the control of Mr. Chaim Lebovits, our President and Chief Executive Officer, we granted ACCBT the right to acquire additional shares of our Common Stock whenever we issue additional shares of Common Stock or other securities of the Company, or options or rights to purchase shares of the Company or other securities directly or indirectly convertible into or exercisable for shares of the Company (including shares of any newly created class or series). This participation right could limit our ability to enter into equity financings and to raise funds from third parties. ACCBT is entitled to purchase its pro rata share of any additional securities we offer, so that its percentage ownership of the Company remains the same after any such issuance of additional securities. Such additional securities will be offered to ACCBT at the same price and on the same terms as the other investors in the transaction. ACCBT will have 30 days from the date of our notice to ACCBT of any intended transaction, to decide whether it wishes to exercise its participation rights in the transaction. We also are prohibited from taking certain corporate actions without the consent of ACCBT, including entering into transactions greater than $ 500, 000. Further, ACCBT also has the right to appoint 30 % of our Board. In connection with the Subscription Agreement, we entered into a registration rights agreement with ACCBT pursuant to which we granted piggyback registration rights to ACCBT. In addition, we issued ACCBT warrants to purchase up to 2, 016, 666 shares of Common Stock, of which 2, 016, 666 warrants are presently outstanding. The outstanding warrants contain cashless exercise provisions, which permit the cashless exercise of up to 50 % of the underlying shares of Common Stock. 672, 222 of such warrants have an exercise price of $ 3. 00 and the remainder have an exercise price of $ 4. 35. We registered 1, 920, 461 shares of Common Stock and 2, 016, 666 shares of Common Stock underlying the ACCBT Warrants on registration statement No. 333- 201705 dated January 26, 2015 pursuant to ACCBT' s registration rights. ACCBT has waived its participation rights and anti- dilution ~~rights~~ **72rights** with respect to issuances that were made on or prior to November 2, 2017. In March 2014, we entered into an agreement with ACCBT according to which ACCBT waived certain anti- dilution rights. On November 2, 2017, the Company entered into a Warrant Amendment Agreement with ACCBT, pursuant to which the expiration date of each Warrant held by ACCBT was extended until November 5, 2022, in consideration of ACCBT having provided a series of waivers of their rights and reduction of rights. You may experience difficulties in attempting to enforce liabilities based upon U. S. federal securities laws against us and our non- U. S. resident directors and officers. Our principal operations are located through our subsidiary in Israel and our principal assets are located outside the U. S. Our Chief Executive Officer and Chief Business Officer and some of our directors are foreign citizens and do not reside in the U. S. It may be difficult for courts in the U. S. to obtain jurisdiction over our foreign assets or these

persons and as a result, it may be difficult or impossible for you to enforce judgments rendered against us or our directors or executive officers in U. S. courts. Thus, should any situation arise in the future in which you have a cause of action against these persons or entities, you are at greater risk in investing in our company rather than a domestic company because of greater potential difficulties in bringing lawsuits or, if successful, collecting judgments against these persons or entities as opposed to domestic persons or entities. If we fail to implement and maintain an effective system of internal controls, we may be unable to accurately report our results of operations or prevent fraud, and investor confidence and the market price of our Common Stock may be materially and adversely affected. As a public company in the United States, we are subject to the reporting obligations under the U. S. securities laws. The SEC, as required under Section 404 of the Sarbanes- Oxley Act of 2002, has adopted rules requiring every public company to include a report of management on the effectiveness of such company' s internal control over financial reporting in its annual report. In prior years, management has identified material weaknesses in our internal control over financial reporting. If any of our prior material weaknesses recurs, or if we identify additional weaknesses or fail to timely and successfully implement new or improved controls, our ability to assure timely and accurate financial reporting may be adversely affected, and we could suffer a loss of investor confidence in the reliability of our financial statements, which in turn could negatively impact the trading price of our shares of Common Stock, result in lawsuits being filed against us by our stockholders, or otherwise harm our reputation. If material weaknesses are identified in the future, it could be costly to remediate such material weaknesses, which may adversely affect our results of operations. In addition, our auditor is not required to attest to the effectiveness of our internal controls over financial reporting due to our status of qualifying as a smaller reporting company. As a result, current and potential investors could lose confidence in our financial reporting, which could harm our business and have an adverse effect on our share price. ~~76~~ **Delaware law could discourage a change in control, or an acquisition of us by a third party, even if the acquisition would be favorable to you, and thereby adversely affect existing stockholders. The Delaware General Corporation Law contain provisions that may have the effect of making more difficult or delaying attempts by others to obtain control of our company, even when these attempts may be in the best interests of stockholders. Delaware law imposes conditions on certain business combination transactions with " interested stockholders. " These provisions and others that could be adopted in the future could deter unsolicited takeovers or delay or prevent changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests. We do not expect to pay dividends in the foreseeable future, and accordingly you must rely on stock appreciation for any return on your investment. We have paid no cash dividends on our Common Stock to date, and we currently intend to retain our future earnings, if any, to fund the continued development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Further, any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors, including contractual restrictions to which we may be subject, and will be at the discretion of our Board. 73**