

BrainStorm Issues 2024 Letter to Shareholders

NEW YORK, Dec. 30, 2024 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today issued a Letter to shareholders.

Dear Valued Shareholders,

2024 has been a very productive year for BrainStorm Cell Therapeutics, defined by remarkable milestones and achievements that have brought us closer to our mission of delivering groundbreaking therapies for neurodegenerative diseases. I am proud to share this summary of our accomplishments as we close the year with optimism and look forward to the promise of 2025.

2024: A Year of Strategic Milestones

This year, we achieved one of our most significant milestones to date - securing a Special Protocol Assessment (SPA) with the US Food and Drug Administration (FDA) for our Phase 3b clinical trial of NurOwn®. An SPA agreement ensures that critical elements of a clinical trial's overall design and analysis plan are adequate to support regulatory approval of a drug, significantly de-risking the regulatory aspects of our clinical development pathway. Additionally, in June, we announced that we had reached alignment with the FDA on our Chemistry, Manufacturing, and Controls (CMC) plan for our Phase 3b clinical trial, laying the groundwork for a consistent and high-quality manufacturing process essential for clinical success.

Operationally, we fortified our capabilities by entering a Memorandum of Understanding (MOU) with Pluri Inc. for the clinical manufacturing of NurOwn. Pluri's expertise in GMP-compliant manufacturing will complement our already leased facility at the Sourasky Medical Center in Tel Aviv (Ichilov) Manufacturing Center in Israel, enabling a fast startup for the Phase 3b study. Furthermore, an additional U.S.-based manufacturing center will be onboarded to support broader production needs as we advance.

On the research front, our advancements have been equally compelling. Data from our biomarker studies continue to demonstrate the potential of NurOwn to reduce neurofilament light (NfL) levels, an important marker of neurodegeneration in ALS patients. NfL is a well-established biomarker linked to axonal damage, and elevated levels are often associated with disease progression in neurodegenerative conditions. In our studies, patients treated with NurOwn have consistently exhibited reductions in NfL compared to baseline levels, suggesting that NurOwn may mitigate the ongoing neuronal damage typically seen in ALS.

These results are particularly meaningful because they provide a quantifiable measure of NurOwn's biological impact, complementing clinical assessments of patient function and quality of life. Beyond NfL, exploratory analyses have highlighted potential correlations between NurOwn treatment and other biomarkers associated with inflammation and neuroprotection, further emphasizing the potential multifaceted benefits of our therapy. Together, these findings validate our scientific approach and reinforce our confidence in NurOwn's ability to deliver meaningful and measurable outcomes for patients battling ALS.

Despite the challenges we faced, including the setback of a disappointing FDA Advisory Committee (ADCOM) meeting in 2023, we have been able to learn from these experiences to refine our strategies and strengthen our alignment with the FDA. These efforts have ultimately positioned us for greater success moving forward. We will continue to work closely with the FDA, as well as with ALS advocacy groups and leading ALS scientists and clinicians, to ensure we remain aligned with both regulatory guidelines and experts' expectations. We wish to thank the dedicated efforts of those in the Center for Biologics Evaluation and Research (CBER), and particularly those in its Office of Therapeutic Products (OTP) for their assistance during the past year toward advancing the program.

On the corporate front, our leadership team has also been strengthened with the addition of DrHaro Hartounian as Chief Operating Officer. Dr. Hartounian's extensive experience in cell and gene therapy, coupled with his operational acumen, will be instrumental in navigating the complexities of manufacturing and commercialization. Similarly, Bob Dagher, M.D., has been promoted to Chief Medical Officer. With a successful track record in the development and approval of treatments for challenging neurological and rare diseases, Dr. Dagher has played a pivotal role in advancing our clinical development plans and translating pre-clinical research into clinical applications, further expanding NurOwn into new therapeutic areas.

2025 and Beyond

As we enter 2025, our focus intensifies on executing the Phase 3b trial for NurOwn, a pivotal step that underscores our commitment to the ALS community. Results from our prior Phase 3 study demonstrated that NurOwn is more likely to have a treatment effect in early-stage ALS patients and this is the group we are targeting in Phase 3b. The Phase 3b trial seeks to provide robust evidence of the treatment's efficacy, offering hope to individuals and families affected by this devastating

disease.

Simultaneously, we are accelerating the development of our exosome platform, a groundbreaking approach with significant potential to address critical pathways in neurodegenerative and respiratory diseases. With its customizable, nano-carrier-based solutions, we are pursuing strategic collaborations to expand its therapeutic applications and unlock further value. Advancing the exosome platform into clinical phases will mark a major milestone, reflecting our dedication to both pipeline innovation and stakeholder value. This progress is bolstered by a recent Notice of Allowance from the U.S. Patent and Trademark Office, strengthening our intellectual property portfolio and solidifying BrainStorm's leadership in cell-based therapies.

A Resilient Business and Operational Structures

Despite the inherent challenges of the biotechnology sector, including a difficult financing environment, BrainStorm has consistently achieved remarkable outcomes with limited resources. All the accomplishments highlighted this year reflect our ability to excel despite financial constraints, thanks to the dedication and ingenuity of our world class BrainStorm team. By achieving more with less, we have maintained financial discipline and operational excellence. Strategic partnerships, such as our collaboration with Pluri, and prudent capital management have further positioned us to execute on our ambitious goals. Since the ADCOM results, we have successfully raised approximately \$8 million, and we are actively pursuing additional funding sources, including non-dilutive grants and potential partnerships, to fund Phase 3b trial for NurOwn, development of our exosome platform and our operations. Our team's sacrifices, including salary reductions and extended work hours, have been critical in keeping the company moving forward. We remain committed to exploring new opportunities for funding and collaboration to ensure our innovations reach their full potential.

Reflecting on Our Mission

As we look ahead, it is important to reaffirm the values that drive us. At BrainStorm, innovation is not just a goal - it is our ethos. Our commitment to patients remains steadfast, and our focus on scientific excellence guides every decision we make. Each milestone achieved brings us closer to transforming lives, and we are honored to have your support on this journey.

Closing Thoughts

2024 has been a year of progress, perseverance, and preparation. We are entering 2025 with a renewed sense of purpose and optimism. With the Phase 3b trial on track to launch and our exosome platform advancing, we are poised to deliver on the promise of innovation, and we see multiple opportunities to create value.

Ending the year on a high note, the FDA's approval of Ryonicil, the first mesenchymal stromal cell (MSC)-based therapy, has been a pivotal moment for the regenerative medicine field. This milestone highlights the FDA's commitment to fostering innovative treatments for unmet medical needs. It has given the cell therapy community a renewed sense of optimism for the future, inspiring confidence in our own MSC-based therapeutic approach with NurOwn. Together, we are entering 2025 with momentum and hope for progress that biotech can achieve to transform patient lives.

Thank you for your trust and belief in our vision. Your support is important to our mission to redefine what is possible in the treatment of neurodegenerative diseases. As we enter the next chapter, we invite you to stay engaged with our progress through regular updates, earnings calls, and strategic announcements. Together, we will continue to make progress toward a brighter future.

With gratitude and determination,

Chaim Lebovits
President and Chief Executive Officer
BrainStorm Cell Therapeutics Inc.

December 30, 2024

Notice Regarding Forward-Looking Statements

This letter to shareholders contains "forward-looking statements" that are subject to substantial risks and uncertainties, including statements regarding cooperation with Pluri for the clinical manufacturing of NurOwn, potential partnership with an additional U.S.-based manufacturing center, clinical development of NurOwn as a therapy for the treatment of ALS, the future availability of NurOwn to patients, future strategies with respect to NurOwn and our exosome platform, exploration of new opportunities for funding and collaboration, and the future success of BrainStorm Cell Therapeutics. All statements, other than statements of historical fact, contained in this letter to shareholders are forward-looking statements. Forward-looking statements contained in this letter to shareholders may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on BrainStorm's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. These potential risks and uncertainties include, without

limitation, the factors detailed in BrainStorm's most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q available at <http://www.sec.gov>. These factors should be considered carefully, and readers should not place undue reliance on BrainStorm's forward-looking statements. The forward-looking statements contained in this letter to shareholders are based on the beliefs, expectations, and opinions of management as of the date of this letter to shareholders. We do not assume any obligation to update forward-looking statements to reflect actual results or assumptions if circumstances or management's beliefs, expectations or opinions should change, unless otherwise required by law. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements.

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