UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PLAINTIFF, Individually and on behalf of all others similarly situated, Plaintiff, v. BRAINSTORM CELL THERAPEUTICS INC., CHAIM LEBOVITS, and STACY LINDBORG, Defendants.	Case No: CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS JURYTRIALDEMANDED CLASSACTION

Plaintiff, individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, among other things, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants' public documents, public filings, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Brainstorm Cell Therapeutics Inc. ("Brainstorm Cell" or the "Company"), and information

readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired publicly traded Brainstorm Cell securities between August 15, 2022 and September 27, 2023, inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).

4. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) as the alleged misstatements entered and the subsequent damages took place in this judicial district.

5. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants (defined below), directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

6. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Brainstorm Cell securities during the Class Period and was economically damaged thereby.

7. Defendant Brainstorm Cell is a biotechnology company, which develops and commercializes autologous cellular therapies for the treatment of neurodegenerative diseases, including Amyotrophic Lateral Sclerosis, Progressive Multiple Sclerosis, Alzheimer's disease, and other neurodegenerative diseases. Its pipeline, NurOwn proprietary cell therapy platform, leverages cell culture methods to induce autologous bone marrow-derived mesenchymal stem cells to secrete high levels of neurotrophic factors, modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival, and improve neurological function.

8. Defendant Brainstorm Cell is incorporated in Delaware and its principal office is located at 1325 Avenue of Americas, 28th Floor, New York, New York, 10019. Brainstorm Cell securities trade on the Nasdaq Stock Market ("NASDAQ") under the ticker symbol "BCLI."

9. Defendant Chaim Lebovits ("Lebovits") has served as the Company's President since July 2007 and Co-Chief Executive Officer ("CEO") since September 2015.

10. Defendant Stacy Lindborg ("Lindborg") has served as the Company's Co-CEO since June 2020.

11. Defendants Lebovits and Lindborg, are collectively referred to herein as the "Individual Defendants."

12. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

13. The Company is liable for the acts of the Individual Defendants and its employees under the doctrine of respondeat superior and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

14. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Brainstorm Cell under respondeat superior and agency principles.

15. Defendant Brainstorm Cell and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS
Materially False and Misleading Statements Issued During the Class Period

16. On August 15, 2022, before market hours, the Company issued a press release announcing its submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for NurOwn for the treatment of amyotrophic lateral sclerosis ("ALS").

The press release touted the effectiveness of NurOwn, by stating the following, in relevant part:

> BrainStorm announces decision to submit a BLA to the FDA for NurOwn® for the treatment of ALS
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> "Brainstorm Cell Therapeutics is at a pivotal moment as a company as we finalize the regulatory filing for NurOwn® in the treatment of ALS. The continued analysis and the feedback received from the many scientific presentations of NurOwn's® Phase 3 data have uncovered key insights that furthered our understanding of the product mechanism of action and therapeutic potential and strengthened the conclusions of NurOwn's® efficacy," said Chaim Lebovits, Chief Executive Officer. "After carefully considering these learnings, the totality of the evidence from NurOwn's® clinical studies, and the feedback received from key opinion leaders and the broader ALS community, we will submit a Biologics License Application to the FDA. We are deeply grateful to the ALS clinical experts, members of the ALS community and faithful investors for their contribution to the development of NurOwn® and what it may mean to those living with ALS. Their contributions and commitment made our current progress possible and continue to inspire us as we prepare for the considerable work ahead. We intend to provide additional updates upon learning whether the FDA files our BLA submission."
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> New clinical analyses strengthen the conclusions from NurOwn's® Phase 3 clinical trial
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> A correction was made to the Muscle and Nerve publication from December 2021 describing the results of NurOwn's® Phase 3 clinical trial in ALS following new clinical analyses which strengthen the Company's original conclusions from the trial. The correction results in a statistically significant treatment difference ($p=0.050$) of more than 2 points for an important secondary endpoint, average change from baseline in ALSFRS-R, in the pre-specified efficacy subgroup of participants with a baseline score of at least 35. Analyses reported in the original publication utilized an efficacy model that unintentionally deviated from the trial's pre-specified statistical analysis plan by erroneously incorporating interaction terms between the subgroup and treatment. The newly published results, which includes supporting information to the publication, employ the efficacy model as pre-specified in the trial's statistical analysis plan, correcting the analyses. The correction also relates to the other subgroup analyses published for this endpoint, demonstrating that all subgroups with ALSFRS-R baseline scores of at least 26 to 35 showed a statistically significant benefit following treatment with NurOwn® ($p\leq0.050$) on this secondary endpoint.

(Emphasis added).

17. On October 12, 2022, after market hours, the Company issued a press release

announcing the presentation of new biomarker analyses from its NurOwn Phase 3 ALS study. The press released continued to tout the effectiveness of NurOwn, stating the following, in relevant part:

> "The new biomarker analyses presented today provide further evidence of NurOwn's multifaceted mechanism of action and show consistent patterns in study participants regardless of the level of disease progression at baseline," said Dr. Stacy Lindborg, Chief Development Officer at Brainstorm. "This compelling finding confirms the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints in our phase 3 trial and may further validate the results of subgroup analyses on clinical endpoints in our Phase 3 study which minimize the ALSFRS-R floor. When the subgroup of participants above 26 are analyzed, 2 points of function are preserved on average across 28 weeks in participants treated with NurOwn compared to placebo ($p<.05$). Moreover, statistical modeling identified biomarkers that have the potential to predict clinical response to NurOwn observed in the trial, with markers of neuroinflammation, neurodegeneration, and neuroprotection selected in the final model. Novel therapies that simultaneously target multiple pathways may offer great potential in the treatment of ALS and highlights the advantages that may come with NurOwn's ability to simultaneously modulate multiple biological pathways.
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> * * *
>
> BiomarkerData
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> - An analysis was performed to evaluate the effects of NurOwn and placebo on cerebrospinal fluid (CSF) biomarkers across pathways important to ALS of neuroinflammation, neurodegeneration and neuroprotection. Additional goals were to understand the role that baseline ALSFRS-R values plays on biomarker trajectories and to understand the predictive power of biomarkers on clinical outcomes.
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> - As observed in earlier trials, NurOwn was shown to decrease biomarkers associated with neuroinflammation and neurodegeneration, and increase neuroprotective biomarkers over 20 weeks, demonstrating its multifaceted mechanism of action.
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> - New analyses looked at the trajectory of biomarkers for the subgroups of participants with baseline ALSFRS-R scores >25 and ≤25, those most likely to be impacted by the floor effect of the scale. Decreases in neuroinflammatory and neurodegenerative markers and increases in neuroprotective markers in NurOwn treated participants compared to placebo were observed in both subgroups. These results indicate that NurOwn had similar biological effects on ALS participants regardless of the level of disease progression at baseline.

- Further statistical modeling pre-specified prior to unblinding of the data identified three biomarkers that were predictive of clinical outcomes: baseline LAP, baseline neurofilament light (NfL) and mean change in Galectin-1. These biomarkers relate to neuroinflammatory, neurodegenerative, and neuroprotective pathways, respectively.

  Chaim Lebovits, Chief Executive Officer of Brainstorm commented, "We are grateful to ALS ONE for the opportunity to present these important new data on NurOwn. The biomarker data and statistical analyses further our understanding of NurOwn's mechanism of action and therapeutic potential."

(Emphasis added).

18. On November 10, 2022 the Company issued a press release entitled "BrainStorm Cell Therapeutics Receives Refusal to File Letter from FDA for its New Biologics License Application for NurOwn for the treatment of ALS." The press release stated the following, in relevant part:

> "While we are disappointed that the FDA has not accepted our BLA for NurOwn in ALS, we remain committed to NurOwn's advancement as a treatment for this devastating disease. The company intends to request a Type A meeting and looks forward to continued discussions with the FDA," said Chaim Lebovits, Chief Executive Officer of BrainStorm. "We continue to believe that NurOwn's Phase 3 trial represents a significant contribution to ALS therapy and will continue to work tirelessly to address the needs of people living with ALS by advancing science and partnering with researchers around the world."
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> The three, co-principal investigators of the NurOwn Phase 3 study were Dr. Robert Brown, Director of the Program in Neurotherapeutics at the University of Massachusetts Medical School, Dr. Merit Cudkowicz, Chief of Neurology at Massachusetts General Hospital, Julieanne Dorn Professor of Neurology at Harvard Medical School, Director of the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital and Dr. Tony Windebank, Professor of Neurology and Judith and James Pape Adams Foundation Professor of Neuroscience at Mayo Clinic.
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> Drs. Brown, Cudkowicz and Windebank jointly stated, "While the pre-specified primary outcome measure was not met, there were participants with beneficial clinical effects and overall changes in relevant biomarkers of drug effect. Understanding whether there are people with ALS who might respond better to NurOwn is important given the unmet therapeutic need. As the

three co-PIs of the Phase 3 study of NurOwn, we support continued discussions with the FDA on the best path forward."

BrainStorm completed a Phase 3 trial in 200 participants with ALS (Cudkowicz et al.,2022MuscleandNerve). In the attempt to examine a real-world population, the study enrolled people with more advanced disease than other late-stage ALS trials. In fact, more than a third of these participants with advanced disease entered the trial with the one or more dimensions of physical function (e.g., dressing/hygiene, cutting food, walking) starting at the lowest possible score of 0 on the ALSFRS-R; thereby preventing the measurement of further deterioration. A pre-specified subgroup of participants, with baseline ALSFRS-R³35, which controls for this "scale effect" showed a trend to a meaningful increase in the clinical response with NurOwn compared to placebo. The secondary endpoint, average ALSFRS-R change from baseline to 28 weeks in this subgroup, was statistically significant (p=0.050, Muscle and Nerve Supplemental File and Muscle and Nerve Erratum). In addition, post-hoc sensitivity analyses were presented last week (21st Annual NEALS Meeting 2022) which also showed a statistical trend towards a clinically meaningful treatment effect with NurOwn across subgroups, and one that is consistent with the pre-specified subgroup of participants with less advanced ALS at baseline. Finally, biomarker data in all trial participants also showed consistent patterns of NurOwn reducing markers of inflammation and neurodegeneration, and increasing neuroprotective and anti-inflammatory markers relative to placebo, further supporting the notion that trial participants taking NurOwn are indeed experiencing a positive biological effect (ALS ONE Research Symposia 2022).

(Emphasis added).

19. This announcement shocked the market. Brainstorm Cell's share price fell $1.22 per share, or 42.21%, to close at $1.67 per share on November 10, 2023.

20. On November 14, 2022, before market hours, the Company issued a press release on Form 8-K announcing its request for a Type A meeting with the FDA to "facilitate NurOwn's advancement following receipt of a refusal to file letter regarding the Company's new [BLA]." The press release downplayed the refusal to file letter, continuously touting NurOwn's effectiveness. The press release stated the following, in relevant part:

"Our commitment to ALS patients and our belief in NurOwn's potential to address their unmet medical needs remains unchanged, despite our receipt of a

refusal to file letter regarding our new Biologics License Application," said Chaim Lebovits, Chief Executive Officer of Brainstorm. "Our next step is to request a Type A meeting with the FDA, which will help us explore the best path forward to accomplish our goal of providing ALS patients with broad access to NurOwn. We believe that an important part of the regulatory process will be an FDA Advisory Committee meeting to discuss NurOwn, as this will allow a fair hearing in an open and transparent setting. We are grateful for the support we are receiving and look forward to providing more information on our Earnings Call around the FDA feedback we have received, and our next steps."

Third Quarter 2022 and Recent Highlights

- Additional analyses from NurOwn's Phase 3 ALS trial that account for measurement limitations in the lower part of the Revised ALS Functional Rating Scale (ALSFRS-R) were presented at the 21st Annual NEALS Meeting. These analyses add to the robust body of evidence supporting a clinically meaningful treatment effect with NurOwn in ALS, as two complementary post-hoc sensitivity analysis methods showed that, after controlling for the impact of the ALSFRS-R floor effect, participants treated with NurOwn had a higher rate of clinical response and less function lost across 28 weeks compared to placebo.

- Biomarker analyses from NurOwn's Phase 3 ALS trial presented at the 5th Annual ALS ONE Research Symposium confirmed the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints. The new biomarker data presented indicate that NurOwn had similar biological effects on Phase 3 trial participants regardless of the level of disease progression at baseline, providing further evidence confirming NurOwn's multifaceted mechanism of action. Furthermore, biomarkers spanning the 3 key pathways of neurodegeneration, neuroinflammation and neuroprotection were identified by a pre-specified model linking the changes in biomarkers in participants treated with NurOwn to the clinical outcomes observed in the trial. The presentation was delivered by Dr. Stacy Lindborg, Executive Vice President and Chief Development Officer at Brainstorm.

- Full results from a single-arm, Phase 2 trial of NurOwn were published in the peer-reviewed Multiple Sclerosis Journal. The results demonstrate NurOwn's safety and provide preliminary evidence of efficacy in patients with progressive multiple sclerosis (MS). Treatment with NurOwn resulted in large, clinically meaningful improvements in some progressive MS patients, as defined by response criteria, across all endpoints measured. These observed improvements diverged from what was seen in matched patients with progressive MS from the Comprehensive Longitudinal Investigation of Multiple Sclerosis (CLIMB) registry. In addition, biomarker analyses confirmed NurOwn's proposed mechanism of action in progressive MS by showing consistent treatment effects in neuroinflammation and neuroprotection pathways.

- Biomarker data from the Phase 2 trial of NurOwn in progressive MS was presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) by Jeffrey Cohen, MD, Hazel Prior Hostetler Endowed Chair and Professor of Neurology, Cleveland Clinic Lerner College of Medicine, Director, Experimental Therapeutics, Mellen Center for MS Treatment and Research. The presented data provide important biological context for the trial's observed clinical outcomes, as they showed NurOwn treatment resulting in robust increases in neuroprotective biomarkers in cerebrospinal fluid.

(Emphasis added).

21. On March 27, 2023, before market hours, the Company issued a press release announcing the FDA Advisory Committee Meeting to review the Company's BLA of NurOwn. The press release continued to express NurOwn's effectiveness, stating the following, in relevant part:

> Given the goal to proceed to an ADCOM as expeditiously as possible, BrainStorm requested that the Center for Biologics Evaluation and Research (CBER) utilize the FDA's File Over Protest procedure and has filed an amendment to the BLA which responds to most of the outstanding questions the FDA has posed.
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> "The FDA provided us with more than one path to an ADCOM for NurOwn. Our goal has always been to make NurOwn available to people living with ALS as quickly as possible, therefore we chose the File Over Protest pathway since this offered the fastest path to an ADCOM and regulatory decision relative to other pathways provided by the FDA," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "The ALS community needs additional treatment options now, and we firmly believe our data support regulatory approval of NurOwn. We are grateful to the FDA for the opportunity to have the clinical evidence supporting NurOwn reviewed."
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> Stacy Lindborg, Ph.D., BrainStorm's Co-Chief Executive Officer commented, "ALS is a horrific, neurodegenerative disease that moves at a terrifying speed, robbing people of their ability to move, speak, eat, and breathe. Securing an ADCOM represents an important step towards our goal of making NurOwn broadly available to individuals living with ALS who are in urgent need of new, effective therapies. The meeting will provide an open forum for BrainStorm and the FDA, together with medical experts, statisticians, and the ALS community, to thoughtfully review all available evidence supporting NurOwn. We remain confident in NurOwn and we are committed to doing everything in our power to make the product available quickly to people living with ALS. We look forward to a robust scientific discussion."

(Emphasis added.)

22. On March 30, 2023, before market hours, the Company issued a press release reminding investors about the upcoming FDA Advisory Committee Meeting. The press release continued to express NurOwn's effectiveness, stating the following, in relevant part:

> "Our priority in 2023 is to advance NurOwn® through the regulatory process as expeditiously as possible, including making preparations for our upcoming Advisory Committee Meeting," said BrainStorm's President and Chief Executive Officer (CEO) Chaim Lebovits and Co-CEO Dr. Stacy Lindborg in a joint statement. "The ADCOM will provide an invaluable opportunity for an open and thoughtful discussion among BrainStorm, regulators, ALS experts, and other key stakeholders on both the urgent need for new ALS therapies and the robust and intricate dataset that we believe supports NurOwn's approval. As we move towards this important event, our clinical trial results and experienced team give us confidence in our ability to secure a successful outcome and execute on our mission of improving the lives of individuals with ALS."
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> Fourth Quarter 2022 and Recent Highlights
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> U.S. Food and Drug Administration (FDA) notified BrainStorm in a written communication that the Agency will hold an Advisory Committee Meeting (ADCOM) to review the company's Biologics License Application (BLA) for NurOwn for the treatment of amyotrophic lateral sclerosis (ALS).

- To meet its goal of proceeding to an ADCOM as expeditiously as possible, BrainStorm utilized the FDA's File Over protest procedure to return the BLA to active review and filed an amendment which responds to most of the outstanding questions previously posed by the FDA. The Agency notified Brainstorm that it will set a date for the ADCOM as well as a Prescription Drug User Fee Act (PDUFA) target action date in due course.

- A presentation at the 2023 MDA Clinical and Scientific Conference delivered by Dr. Lindborg featured post hoc sensitivity analyses from NurOwn's Phase 3 ALS trial. The presentation showed that a floor effect was observed in the PRO-ACT database, and a pattern of a plateau in ALSFRS-R total score was accompanied by scale items of 0 suggesting measurement challenges in those with advanced ALS due to the floor effect of the ALSFRS-R in the NurOwn phase 3 trial and historical studies which are included in the PRO-ACT database. Analyses conducted in participants not impacted by the floor effect at baseline of the NurOwn phase 3 trial revealed statistically significant, clinically meaningful effects with NurOwn on the primary and key secondary endpoints.

- Additional analyses from the Phase 3 trial of NurOwn in ALS were featured in a presentation at the 21st Annual NEALS Meeting. These analyses further strengthened the body of evidence supporting a clinically meaningful treatment

effect with NurOwn in ALS. Two complementary post-hoc sensitivity analysis methods showed that, after controlling for the impact of the ALSFRS-R floor effect, participants treated with NurOwn had a higher rate of clinical response and less function lost across 28 weeks compared to placebo. The presentation was co-delivered by Dr. Lindborg and Merit Cudkowicz, MD, MSC, Chief of Neurology at Massachusetts General Hospital, Julieanne Dorn Professor of Neurology at Harvard Medical School, and Director of the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital.

- Biomarker data from the Phase 3 trial of NurOwn in ALS were featured in a presentation delivered by Dr. Lindborg at the 5th Annual ALS ONE Research Symposium. The data showed NurOwn modulated pathways related to neurodegeneration, neuroinflammation, and neuroprotection, with changes that were consistent regardless of a participant's level of disease progression at baseline. These data provide further evidence of NurOwn's multifaceted mechanism of action and of the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints.

- Findings from the Phase 3 trial of NurOwn in ALS, including biomarker data and analyses accounting for the ALSFRS-R floor effect, were presented at the 13th Annual California ALS Research Summit by Dr. Lindborg. The presentation demonstrated that NurOwn had significantly better outcomes in analyses controlling for the floor effect. Outcomes that aligned with historical data and power calculations of the trial.

- Biomarker data from the Phase 2 trial of NurOwn in progressive multiple sclerosis were presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). The data showed robust increases in levels of neuroprotective biomarkers in cerebrospinal fluid with NurOwn treatment, thereby providing important biological context for clinical outcome data showing large, clinically meaningful improvements in some trial participants, as defined by response criteria, across all endpoints measured. These observed improvements diverged from what was seen in matched patients with progressive MS from the Comprehensive Longitudinal Investigation of Multiple Sclerosis (CLIMB) registry. The presentation was delivered by Jeffrey Cohen, MD, Hazel Prior Hostetler Endowed Chair and Professor of Neurology, Cleveland Clinic Lerner College of Medicine, Director, Experimental Therapeutics, Mellen Center for MS Treatment and Research.

(Emphasis added).

23. On June 6, 2023, before the market opened, the Company issued a press release announcing the FDA's plan to meet on September 27, 2023 to review the BLA for NurOwn. The

press release continued to make positive statements about NurOwn, stating the following, in relevant part:

> "We are encouraged by the regulatory flexibility that the FDA has shown over the last year in ALS broadly, and with respect to NurOwn in particular, and believe an Advisory Committee meeting is good for patients," said Chaim Lebovits, BrainStorm President & CEO. "We are of course deeply committed to the scientific and regulatory process, which includes continuing research to confirm the results of the NurOwn clinical program and are working with ALS experts in designing a rigorous clinical study to answer important questions about this therapy and inform further research on ALS."
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> Stacy Lindborg, Ph.D., BrainStorm co-CEO, commented: "We welcome the opportunity to present our data at the forthcoming ADCOM. We remain confident in NurOwn and believe our data support regulatory approval. As is the case with most ALS research, our clinical program generated complex results, which deserve a thoughtful and holistic review by scientists, ALS experts, FDA reviewers, advocates, and patients. We believe this approach honors the needs of those living with ALS and offers the greatest promise for BrainStorm to fulfill our commitment to the ALS community."

(Emphasis added).

24. On August 14, 2023, before the market opened, the Company issued a press release restating its preparations for its meeting with the FDA on September 27, 2023 to review the BLA for NurOwn. The press release continued to make positive statements about NurOwn, stating the following, in relevant part:

> BrainStorm's immediate priorities are to prepare for the upcoming ADCOM meeting to review the BLA for NurOwn®, scheduled for September 27, and complete preparations for commercial launch. The Company's senior team is working with expert consultants to ensure it will deliver a compelling presentation to the ADCOM and is prepared to address the questions that the FDA and members of the committee might raise.
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> "We appreciate the FDA's guidance and input throughout the review process, which will be instrumental in making a policy decision that meets the needs of those living with ALS," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "In parallel with the regulatory work, we are preparing the company for success, with the goal of making NurOwn available to patients, if approved in December."

Dr. Stacy Lindborg, Co-Chief Executive Officer of BrainStorm commented, "We look forward to discussing NurOwn's full dataset at the forthcoming ADCOM meeting. Our clinical program has generated complex results, and the ADCOM meeting will provide us with the opportunity for a thoughtful discussion with scientists, ALS experts, FDA reviewers, advocates, and patients. We have full confidence in the data we have compiled, and believe that a comprehensive analysis of our results strongly supports NurOwn's clinically meaningful effectiveness. In addition, we continue to share our data with the ALS community at scientific meetings and recently delivered an important presentation at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference. The data from this new analysis showed that treatment with NurOwn significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, including neurofilament light (NfL). Reductions in plasma NfL are believed to be a predictor of clinical benefit in ALS."

Second Quarter 2023 and Recent Highlights

Clinicalandregulatory

- The U.S. Food and Drug Administration (FDA) notified BrainStorm that a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee to review the BLA for NurOwn® has been scheduled for September 27, 2023. In addition, BrainStorm's BLA for NurOwn has been assigned a PDUFA action date targeted to occur by December 8, 2023.
- In July 2023, new biomarker data from the Phase 3 trial of NurOwn were presented at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference. These data show that treatment with NurOwn significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, including NfL over time compared to placebo in all trial participants. It is believed that reductions in plasma NfL are reasonably likely to predict clinical benefit in ALS.

(Emphasis added).

25. The statements contained in ¶¶ 16-24 were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) Brainstorm Cell downplayed the severity of the FDA's refusal to file

letter; (2) Brainstorm Cell continued to conceal the risks associated with the submission of the BLA; and (3) as a result, Defendants' statements about its business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

THE TRUTH BEGINS TO EMERGE

26. On September 27, 2023, the Company announced in a press release the results of the FDA's review of its BLA. Members of the Cellular, Tissue, and Gene Therapies Advisory Committee voted 17 to 1 that there was not substantial evidence to show NurOwn's effectiveness. The press release stated the following, in relevant part:

> Today the Committee voted that NurOwn did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS.
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> "The Committee's vote was a sad outcome for the ALS community, who have too few options to help manage this merciless and deadly disease," said Stacy Lindborg, PhD, co-CEO of BrainStorm. "We firmly believe that the totality of data presented for NurOwn today provide a compelling case for approval, with clinical evidence in those with less advanced disease supported by strong and consistent biomarker data that are predictive of clinical response. We truly did our best to make the NurOwn data clear to the FDA Advisory Committee. Unfortunately, had more time and opportunity been allowed, many remaining questions posed by Advisory Committee members could have been sufficiently addressed."

27. The FDA briefing document revealed Brainstorm Cell severely downplayed the risks associated with NurOwn, stating the following, in relevant part:

> On initial receipt of the BLA, FDA determined that the submission was scientifically incomplete to demonstrate substantial evidence of effectiveness, and that the manufacturing information was grossly deficient to ensure adequate product quality. Examples of critical information not provided in the BLA submission include missing or inadequate control of materials, validation of methods missing or incomplete, lack of data demonstrating manufacturing consistency, control strategy for prefilled syringe not provided, inadequate manufacturing and testing facility information, and facilities not ready for inspection.
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> FDA therefore refused to file the submission and detailed these deficiencies in a Refuse to File (RTF) letter to the Applicant. The Applicant elected to request that

the BLA to be filed over protest, and subsequently provided further retrospective analyses and biomarker results.

* * *

(2) Survival in the Phase 3 study was worse at study completion for subjects who received MSC-NTF. A total of 13 deaths occurred during the post-treatment follow up (28 weeks ± 5 days) with 10 deaths (10/95) in the MSC-NTF group and 3 deaths (3/94) in the placebo group. The Kaplan-Meier (KM) estimate of survival at Week 28 (± 5 days) was 88.3% (95% CI: 79.3, 93.6) for the MSC-NTF group and 94.4% (95% CI: 81.2, 98.4) for the placebo group, with a nominal pvalue of 0.04 from unadjusted log rank test.

This outcome suggests the lack of efficacy of MSC-NTF on survival of patients with ALS.

(3) The Applicant performed three different retrospective analyses on an unblinded, post-hoc subgroup from the Phase 3 study, excluding in each certain subjects based on the assertion of a "floor effect" in the ALSFRS-R, according to different criteria. A floor effect refers to insensitivity of an outcome measure to differences at the lower end of an assessment scale. In this case, the Applicant claims that a floor effect results in plateauing of ALSFRS-R total scores over time, during which further deterioration of function cannot be measured. However, no floor effect was demonstrated in the analyses. In addition, floor effect would not be expected in the assessment of survival or biomarkers. Of note, when assessed by change in ALSFRS-R total score from baseline to Week 28, the MSCNTF subjects ostensibly affected by a "floor effect" in fact experienced a numerically larger decline in function over time than did the corresponding placebo subjects. This result indicates continued deterioration of function and suggests lack of treatment benefit for MSC-NTF subjects.

(4) In the Phase 3 study, the Applicant collected cerebrospinal fluid (CSF) samples at baseline, Weeks 2, 4, 8, 12, 16, and 20 post-Treatment 1, and examined levels of multiple biomarkers. The Applicant then conducted numerous exploratory analyses, including multiple post hoc analyses, to evaluate the relationships between the selected biomarkers and clinical efficacy outcomes, to support the claim of effectiveness. Of note, there was a large amount of missing data for all biomarkers at Week 20 (~50%), the last time point for biomarker sample collection and the focused time point for biomarker analyses.

* * *

The Applicant submitted the BLA on September 9, 2022. FDA conducted a filing review and determined that a substantive review could not be performed, because the BLA submission was scientifically incomplete and grossly deficient. Critical clinical and manufacturing deficiencies were identified. For clinical, the

completed randomized, placebo-controlled clinical studies failed to show efficacy in their prospectively specified efficacy endpoints to demonstrate required substantial evidence of effectiveness. For manufacturing, the required Chemistry, Manufacturing, and Controls information covering several critical categories was not included in the application, and the level of information included was insufficient to perform a full assessment of product quality. Consequently, FDA issued a refuse-to-file letter to the Applicant on November 8, 2022.

* * *

FDA has concerns about the consistency of the manufacturing process and potential sources of product variability. It is important for licensure the Applicant demonstrate the manufacturing process is under a state of control. Chemistry, Manufacturing, and Control regulations are intended to assure that all subjects receive a quality product lot, including for safety and potency. Data supporting a product can come from in-process and final product properties, and from clinical data of safety and efficacy. However, for this BLA clinical data supporting safety for all patients is unclear, and efficacy has not been demonstrated.

* * *

In addition to concerns about the adequacy of the existing manufacturing control strategy, there are concerns about manufacturing changes – either those that occurred during clinical development under IND, or for the proposed commercial product.

* * *

The primary efficacy endpoint and all key secondary endpoints failed to demonstrate efficacy of MSC-NTF compared to placebo (see Appendix III).

From the statistical perspective, when the primary efficacy endpoint in a clinical study fails to show statistical significance, the secondary efficacy endpoints cannot be tested with Type I error control.

In accordance with the Agency's discussions with the Applicant (Face-to-Face Meeting, November 18, 2019), however, FDA reviewed all primary and key secondary endpoint results. The Agency did so for several reasons: (1) although at that meeting the Applicant expressed openness to changing the primary efficacy endpoint from a slope-based analysis, FDA recommended against doing so, in order to avoid compromising the integrity of the Phase 3 study, which the Applicant had already initiated; (2) data for the outcome measures recommended by the Agency, such as CAFS or survival, were collected by the Applicant as secondary efficacy endpoints; and (3) FDA's willingness to exercise regulatory flexibility and desire to better inform subjects and stakeholders.

PrimaryEfficacyEndpoint

For the Applicant's primary efficacy endpoint, the percent of responders in the MSC-NTF group versus the placebo group did not show a statistically significantly difference: the MSC-NTF group had 32.6% (31/95) responders and the placebo group had 27.7% (26/94). The odds ratio after adjusting for the predefined covariates was 1.33 (95% CI: 0.63, 2.80) with a p-value of 0.45.

KeySecondaryEfficacyEndpoints

All key secondary efficacy endpoints failed to show efficacy of MSC-NTF. For example, the least squares (LS) mean CAFS scores at Week 28 did not differ significantly between subjects in the MSC-NTF group and those in the placebo group (3.0: 96.5 versus 93.5; 95% CI: -11.4, 17.4; nominal p-value:17 0.68). Similarly, there was minimal difference in LS mean change from baseline to Week 28 in ALSFRS-R total score (0.4: –5.5 versus –5.9; 95% CI: -1.47, 2.20; nominal p-value: 0.69).

* * *

In addition to this analysis, at the Type A meeting with the FDA after refusal to file of the BLA, the Applicant presented a third post-hoc floor effect analysis in which the no floor effect subgroup was defined as ALSFRS-R Item Level had no value 0 at baseline (Definition 3).

We will refer to these subgroups identified by the Applicant collectively as "no floor effect subgroup" and their respective complement "floor effect subgroup." In the "no floor effect subgroup" identified by different definitions, some of the clinical endpoints showed "statistical significance" per the Applicant (Appendix IV); however, FDA believes these findings from the exploratory subgroup analysis can only be used for hypothesis generation, not as evidence of effectiveness to support approval, for the following reasons:

> (1) Post-hoc subgroup analyses in general have high risk of finding false positive results due to lack of control for multiple hypothesis testing and potential confounding due to imbalance in the measured/unmeasured baseline prognostic factors brought about by breaking the randomization. What is particularly concerning in this case is that there is no solid definition for the "no floor effect subgroup" (i.e., subgroup of trial subjects not impacted by floor effect). The "no floor effect subgroup" can potentially be defined in many ways, as illustrated by the three distinct subgroups identified by the Applicant, with various sample sizes (145, 159, and 106 subjects respectively). As one could define "no floor effect subgroup" in many ways, some of the "no floor effect subgroup" (like the three selected by the Applicant) may happen to show "positive" findings

(i.e., findings that seem to suggest clinical efficacy) among many other subgroups that may show "negative" findings (i.e., findings that seem to suggest harm). These findings could be due to random chance, given the potentially large number of subgroups the Applicant could examine. Therefore, these findings need to be confirmed by additional adequate and well-controlled clinical study(ies) to establish their validity; these findings cannot be used as evidence of effectiveness to meet the statutory standard for this BLA.

(2) MSC-NTF appeared to have a detrimental effect in the floor effect subgroups (Appendix IV). For example, the placebo group had a better CAFS ranking than the MSC-NTF group with a nominal p-value of 0.026 in the floor effect subgroup defined by ALSFRS-R Total Score baseline ≤25 (Definition 1). The floor effect subgroups defined by the other two methods had the same issue. This is not surprising; given that the overall treatment effect was close to zero, when one subgroup happens to show a strong positive treatment effect, the complementary subgroup is highly likely to have a strong negative effect. The "negative" findings in the floor effect subgroup thus may well be false "negative," in the same way that the "positive" findings in the no floor effect subgroup may well be false positives.

(3) FDA did not observe a "floor effect" in the floor effect subgroup defined by any of the three definitions identified by the Applicant. If there were a "floor effect" in the Applicant-identified floor effect subgroup, the ALSFRS-R total score post baseline would have been bounded by a "floor," which would have prevented the score from much further decline. This is in direct contrast with the fact that the MSC-NTF "floor effect subgroup" had a drastically steeper decline in ALSFRS-R total score from baseline compared with the no floor effect subgroup or the placebo floor effect subgroup. At the same time, the magnitude of change between the placebo floor effect subgroup and the placebo no floor effect subgroup were comparable, which further puts into question the validity of the "floor effect" (Figure 12 [using Definition 1] and Figure 14 [using Definition 3]). In addition, the MSC-NTF floor effect subgroup showed substantially worse CAFS ranking than the no floor effect subgroups while the two placebo subgroups were comparable Figure 13. In conclusion, the lack of efficacy of MSC-NTF over placebo cannot be explained by a floor effect.

* * *

The Applicant conducted exploratory subgroup analysis of "rapid progressors" versus "slow progressors." The Applicant defined "rapid progressors" as subjects with ≥2 points decline from screening to baseline (~3 months) in the ALSFRS-R total score; correspondingly, "slow progressors" were defined as subjects with <2

points decline from screening to baseline in ALSFRS-R total score. As FDA stated in the November 18, 2019, Type C Meeting Summary:

"We interpret your Phase 2 data as evidence that your product is not effective in the treatment of ALS. Your proposal that your Phase 2 data suggest benefit for the 'rapid progressors' is most likely overinterpretation of your subgroup analyses. In subgroup analyses, the results for the 'slow progressors' could be interpreted to suggest that your product is harmful to some patients with ALS. However, such subgroup results, for both the 'rapid progressors' and the 'slow progressors', are most likely spurious and misleading, as is often the case for such subgroup analyses. We note that it is not clear why a product that you propose to have neuroprotective and immunomodulatory effects would be beneficial for some patients with ALS and harmful to other patients with ALS. Due to their inconsistency (i.e., opposite effects in 'rapid progressors' versus 'slow progressors'), and the unclear biological plausibility for such inconsistency, your subgroup results do not support that your product has any meaningful activity in the treatment of ALS" [].

Despite FDA's consistent concern about the definition of "rapid progressors," and the exploratory nature of the subgroup findings, the Applicant decided to enroll only "rapid progressors" in the Phase 3 study. For that study, the Applicant modified the definition of a "rapid progressor" to be subjects who experienced at least a 1.0-point decline in ALSFRS-R per month, on average, during the 3-month pretreatment period.

* * *

In Study BCT-002-US, the biomarker analyses were limited by the large amount of missing data. Biomarker data were only collected up to Week 20, but the efficacy data were collected up to Week 28. At Week 20, the key biomarkers that the Applicant identified, NfL, galectin-1, MCP-1, VEGF-A, and LAP, had up to approximately 50% missing data. In general, this degree of missing data compromises the validity of the analyses and could lead to over-estimation of the correlations between the biomarkers and efficacy endpoints. This missing data problem was further exacerbated when those post-hoc subgroup analyses were conducted based on different "floor effect" hypothesis.

Although the Applicant added the biomarker addendum to the statistical analysis plan before the data were unblinded, numerous biomarker analyses were proposed without multiplicity adjustment or formal hypothesis testing. The results from those biomarker analyses can only be considered as exploratory because there was no overall Type I error rate control, and any nominal "statistical significance" claim (nominal $p \leq 0.05$) could be due to chance alone.

Additionally, the applicant conducted multiple post-hoc analyses after the data were unblinded. These post-hoc analyses could be biased as the data are

unblinded and analyses can be made to produce a more favorable result. Thus, post-hoc analyses in general have a high chance of false positive findings.

In summary, FDA does not believe there is sufficient evidence to support that any of the assessed biomarkers is reasonably likely to predict clinical benefit. Considering the potential mechanism of action of MSC-NTF, which may involve multiple pathways, it is challenging to use biomarker data to support effectiveness of MSC-NTF based on exploratory analyses of multiple biomarkers. There were also large amounts of missing data. In the case of NfL, which is released into the CSF by damaged or degenerating axons, higher reduction from baseline at Week 20 of CSF NfL levels were seen in subjects with poorer efficacy outcome (measured by ALSFRS-R score changes from baseline at Week 28), the opposite of what would be expected. These findings could be due to 50% of missing NfL data at Week 20 and relatively overall small changes in NfL in MSC-NTF group. Either way in the setting of negative phase 3 study results, the findings related to NfL do not appear to provide direct evidence on treatment effect through changes in NfL.

* * *

6.2 Safety Summary

(1) The higher incidence of deaths in the MSC-NTF group which indicates lack of survival benefit of MSC-NTF and warrants further investigation.

(2) There appears to be a higher incidence of respiratory failure and dysphagia in the MSC-NTF group.

(3) There appears to be a higher incidence of pain (e.g., coccydynia and back pain) in the MSC-NTF group.

(Emphasis added).

28. That same day, Reuters published an article entitled, "US FDA panel votes against BrainStorm's ALS therapy over effectiveness concern," summarizing the Committee's decision, stating the following in relevant part:

The U.S. Food and Drug Administration's (FDA) staff reviewers said on Monday there is not enough evidence to support NurOwn's effectiveness and that there are large amounts of missing data in the company's application.

"Providing false hope can be ethically problematic and false hope is provided when the probability of a positive outcome is overestimated. And I think that seems to be the case here," said Lisa Lee, one of the panelists.

29. On this news, Brainstorm Cell's share price fell $0.19 per share, or 48.72%, to close

at $0.2 per share on September 28, 2023.

30. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common shares, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

31. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired the Company's securities publicly traded on NASDAQ during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

32. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

33. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

34. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

35. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act was violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and financial condition of the Company;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Defendants caused the Company to issue false and misleading filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false filings;
- whether the prices of the Company securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

36. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

37. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- the Company's shares met the requirements for listing, and were listed and actively traded on NASDAQ, an efficient market;
- as a public issuer, the Company filed periodic public reports;
- the Company regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- the Company's securities were liquid and traded with moderate to heavy volume during the Class Period; and
- the Company was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

38. Based on the foregoing, the market for the Company's securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in the prices of the shares, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

39. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in Affiliated Ute Citizens of the State of Utah v. United States, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

COUNT I

For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder

Against All Defendants

40. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

41. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

42. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

43. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of the Company's securities during the Class Period.

44. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These

defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

45. Individual Defendants, who are the senior officers of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or any other of the Company's personnel to members of the investing public, including Plaintiff and the Class.

46. As a result of the foregoing, the market price of the Company's securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

47. Had Plaintiff and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

48. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

49. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of the Company's securities during the Class Period.

COUNT II
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

50. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

51. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about the Company's false financial statements.

52. As officers of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's' financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

53. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period concerning the Company's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling

persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company's securities.

54. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of himself and the Class, prays for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and designating plaintiff's counsel as Lead Counsel;

(b) awarding damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, together with interest thereon;

awarding plaintiff and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding plaintiff and other members of the Class such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.