UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. OUTLOOK THERAPEUTICS, INC., C. RUSSELL TRENARY III, LAWRENCE A. KENYON, and TERRY DAGNON, Defendants.	**Case No.** **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, 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, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Defendants' public documents, conference calls and announcements made by

Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Outlook Therapeutics, Inc. ("Outlook" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION AND OVERVIEW

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Outlook securities between August 3, 2021 and August 29, 2023, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Outlook is a late clinical-stage biopharmaceutical company that focuses on developing and commercializing monoclonal antibodies for various ophthalmic indications. The Company's lead product candidate is ONS-5010, an ophthalmic formulation of the antibody bevacizumab for the treatment of wet age-related macular degeneration ("wet AMD") and other retina diseases.

3. On August 3, 2021, Outlook announced the topline readout of data from its pivotal Phase 3 NORSE TWO trial of ONS-5010 for the treatment of wet AMD. According to the Company, this data "demonstrated clinically relevant and highly statistically significant results" that supported the submission of a biologics license application ("BLA") to the U.S. Food and Drug Administration ("FDA") for ONS-5010 for the treatment of wet AMD, which the Company planned to submit to the FDA in the first quarter of 2022.

4. On March 31, 2022, investors began to learn the true state of the Company's development of ONS-5010 when Outlook announced that it had submitted the ONS-5010 BLA to the FDA. However, on May 31, 2022, the Company voluntarily withdrew the BLA for ONS-5010 in order to address deficiencies identified by the FDA and to provide additional information that the FDA requested. The Company received additional correspondence from the FDA, but subsequently announced that it had "confirmed the additional information necessary to re-submit the BLA for ONS-5010." On August 30, 2022, Outlook announced that it had resubmitted the BLA.

5. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) there was a lack of substantial evidence supporting ONS-5010 as a

treatment for wet AMD; (ii) Outlook and/or its manufacturing partners had deficient chemistry, manufacturing and controls ("CMC"), as well as other manufacturing concerns, for ONS-5010, which remained unresolved at the time the BLA for ONS-5010 was submitted and then resubmitted to the FDA; (iii) as a result of all the foregoing, the FDA was unlikely to approve the ONS-5010 BLA in its present form; (iv) accordingly, ONS-5010's regulatory and commercial prospects were overstated; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

6. On August 30, 2023, Outlook shocked investors when it issued a press release announcing that the FDA had issued a complete response letter ("CRL") to its BLA for ONS-5010. The Company advised that, "[w]hile the FDA acknowledged the NORSE TWO pivotal trial met its safety and efficacy endpoints, the Agency concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence."

7. On this news, Outlook's stock price fell $1.141 per share, or 80.92%, from a closing price of $1.41 per share on August 29, 2023, to close at $0.269 per share on August 30, 2023.

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

JURISDICTION AND VENUE

9. 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).

10. 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.

11. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Outlook is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

12. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

13. Plaintiff, as set forth in the attached Certification, acquired Outlook securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

14. Defendant Outlook is a Delaware corporation with principal executive offices located at 485 Route 1 South, Building F, Suite 320, Iselin, New Jersey 08830. Outlook's common stock trades in an efficient market on the Nasdaq Stock Market under the ticker symbol "OTLK".

15. Defendant C. Russell Trenary III ("Trenary") served as Outlook's President and Chief Executive Officer ("CEO") at all relevant times.

16. Defendant Lawrence A. Kenyon ("Kenyon") served as Outlook's Chief Financial Officer ("CFO") at all relevant times.

17. Defendant Terry Dagnon ("Dagnon") served as Outlook's Chief Operating Officer ("COO") at all relevant times.

18. Defendants Trenary, Kenyon, and Dagnon are referred to herein collectively as the "Individual Defendants."

19. Defendant Outlook and the Individual Defendants are collectively referred to herein as "Defendants."

20. The Individual Defendants possessed the power and authority to control the contents of Outlook's SEC filings, press releases, and other market

communications. The Individual Defendants were provided with copies of Outlook's SEC filings and/or press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Outlook, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

21. Outlook is a late clinical-stage biopharmaceutical company that focuses on developing and commercializing monoclonal antibodies for various ophthalmic indications. The Company's lead product candidate is ONS-5010, an ophthalmic formulation of the antibody bevacizumab for the treatment of wet AMD and other retina diseases. Outlook was formerly known as Oncobiologics, Inc. and changed its name to Outlook Therapeutics, Inc. in November 2018.

22. According to the Company's SEC filings, Outlook is endeavoring to launch the first FDA-approved ophthalmic formulation of bevacizumab for use in

retinal indications, including for the treatment of wet AMD. The Company describes bevacizumab as a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity.

23. According to the Company, Outlook's BLA registration program for ONS-5010 in wet AMD has involved three clinical trials, referred to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for the clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed at a meeting with the FDA in April 2018 at the end of Phase 2, and the Company filed an investigational new drug application ("IND") with the FDA in the first quarter of calendar 2019.

24. In August 2020, Outlook purportedly achieved the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study.

25. According to the Company, NORSE TWO is a pivotal Phase 3 clinical trial comparing ONS-5010 (bevacizumab-vikg) to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 purportedly showed that ONS-5010 met the primary and key secondary endpoints for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in Best Corrected

Visual Acuity, or BCVA, score was purportedly met and was, according to the Company, both highly statistically significant and clinically relevant.

26. According to Outlook, NORSE THREE is an open-label safety study conducted to ensure that an adequate number of safety exposures to ONS-5010 were available for the initial ONS-5010 BLA submission. In March 2021, the Company reported that the results from NORSE THREE showed a positive safety profile for ONS-5010.

Defendants' Materially False and/or Misleading Statements and Omissions During the Class Period

27. On August 3, 2021, Outlook announced the topline readout of data from its pivotal Phase 3 NORSE TWO trial of ONS-5010 for the treatment of wet AMD. According to the Company, this data showed "***compelling results***";[1] it "demonstrated clinically relevant and highly statistically significant results" that supported the submission of a BLA to the FDA for ONS-5010 for the treatment of wet AMD. The Company stated that it planned to submit the BLA to the FDA in the first quarter of 2022.

28. Outlook's August 3, 2021 press release quoted Defendant Trenary, CEO and President of Outlook, as follows: "***We are delighted with the compelling results*** observed in NORSE TWO, which represent ***a significant and potentially***

[1] Unless otherwise noted, all emphasis herein is added.

transformational milepost for patients suffering from wet AMD." The press release further quoted Defendant Dagnon, Outlook's COO, as stating as follows:

> In meeting both the primary and key secondary endpoints in NORSE TWO with highly significant clinically relevant results, we have achieved the requirements agreed upon with the FDA, and when combined with our previously reported clinical trial results, this completes the clinical package necessary for the submission of our BLA.

29. On August 13, 2021, Outlook issued a press release announcing its financial results for the third quarter of fiscal year 2021. In that announcement, Defendants updated investors as to the status of the ONS-5010 BLA, stating that "Outlook Therapeutics reported positive topline data from its NORSE TWO pivotal Phase 3 clinical trial. The topline data from NORSE TWO demonstrated that ONS-5010 is safe and met the primary and key secondary endpoints for efficacy." In addition, the press release represented that, "***We couldn't be more pleased with the results from our pivotal study, and now with this added confidence in the potential of ONS-5010 backed by data, we are continuing our shift towards commercialization***."

30. Also on August 13, 2021, Outlook filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for its third fiscal quarter ended June 30, 2021 (the "3Q21 10-Q"). With respect to the ONS-5010 BLA and its regulatory history, Defendants stated:

> Our clinical program for ONS-5010 in wet AMD involves three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE

> THREE. We reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study, in August 2020. NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 ***met the primary and key secondary endpoint for efficacy with clinically impactful change observed*** for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters BCVA was met and was ***highly statistically significant and clinically relevant***…. NORSE THREE is an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 are available for the initial ONS-5010 Biologics License Application, or BLA, filing with the FDA. In March 2021 we reported that the results from NORSE THREE provided a positive safety profile for ONS-5010. Accordingly, all three of these clinical trials required for our planned BLA submission in the first quarter of calendar 2022 for wet AMD have been completed.

31. On September 13, 2021, the Company issued a press release in which it announced that the open-label safety study of ONS-5010 "showed no unexpected safety trends and had a safety profile consistent with that of prior published data undertaken by the National Eye Institute." More specifically, the press releases quoted Defendant Trenary as follows:

> ***ONS-5010 has been rigorously tested to support our efforts to provide the first approved ophthalmic formulation of bevacizumab….With the trial data and market insight seen to date, we believe ONS-5010 has the potential to become the cornerstone of care for multiple retinal indications*** and we look forward to working closely with the U.S. Food and Drug Administration and other global regulatory authorities toward our goal of bringing this important therapy to market.

32. Five days later, on September 18, 2021, Defendants again touted the results of its NORSE TWO clinical trial – and the results of ONS-5010 testing

overall – in a press release represented that "full year data ***reinforce strong safety profile consistent with previous trials of ONS-5010*** and with prior published data."

33. With respect to safety and efficacy of ONS-5010, Defendants represented in the September 18, 2021 press release that:

> "***The full 12-month safety data results move us one step closer to providing patients with an FDA-approved, cGMP-produced drug product that meets ophthalmic FDA standards*** and avoids the potential risks of repackaged IV bevacizumab," said C. Russell Trenary III, President and CEO of Outlook Therapeutics.
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> "The success of NORSE TWO continues to solidify the potential of ONS-5010 ophthalmic bevacizumab as a highly effective and safe treatment in treating wet AMD," added Terry Dagnon, Chief Operating Officer of Outlook Therapeutics. "We are excited that the highly statistically significant and clinically relevant results from NORSE TWO demonstrate the potential clinical value of ONS-5010 for patients and will work closely with the FDA and other global authorities to bring this new option to patients, clinicians and payors as quickly as possible."
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> Topline data from NORSE TWO showed that ONS-5010 bevacizumab-vikg met the primary and key secondary endpoints for efficacy with clinically impactful change observed for treated patients.
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> ***
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> In anticipation of potential FDA marketing approval in 2022 for ONS-5010, Outlook Therapeutics has begun commercial launch planning, including manufacturing with drug substance manufacturer FUJIFILM Diosynth Biotechnologies and best-in-class drug product manufacturer Aji Biopharma Services, distribution, sales force planning, physician and payor advisory board outreach, key opinion leader support and payor community engagement.

34. On October 12, 2021, Defendants issued a press release that addressed the NORSE THREE trial of ONS-5010. Entitled "Outlook Therapeutics' Position NORSE THREE Safety Data Presented at 2021 American Society of Retina Specialists for ONS-5010 Ophthalmic Bevacizumab," the press release stated that: "***[t]he strong safety results from NORSE THREE reinforce the safety profile seen across all three NORSE clinical trials for ONS-5010*** and reflect the consistent safety observed both in decades of real-world clinical practice and in prior published research on the use of bevacizumab in ophthalmology."

35. On December 9, 2021, Outlook issued a press release announcing its upcoming presentation at the 14th Asia-Pacific Vitreo-Retina Society. In that announcement, Defendants touted the "exciting" and "highly significant" results from the NORSE TWO trial, representing that Outlook was "one step closer towards providing patients and retina specialists with the first on-label ophthalmic bevacizumab."

36. On December 22, 2021, in announcing Outlook's financial results for fiscal year 2021, Defendants continued to raise investor expectations regarding the ONS-5010 BLA. The press release stated that:

> "The past year has been ***truly transformational*** for Outlook Therapeutics. Our goal was to successfully complete the registration clinical trials for ONS-5010, and we have not only accomplished that but also reported statistically significant and clinically relevant data that

> bolster our confidence as we progress toward our BLA submission and potential FDA approval…. ***This is truly an exciting time, as we believe we are positioning ourselves for success*** and remain dedicated to advancing this program and building shareholder value as we head into 2022," commented Mr. C. Russell Trenary III, President and Chief Executive Officer of Outlook Therapeutics.

37. On December 23, 2021, Outlook filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operational results for its fiscal fourth quarter and year ended September 30, 2021 (the "2021 10-K"). With respect to ONS-5010, in addition to substantively the same statements as referenced in ¶ 30, *supra*, the 2021 10-K stated with respect to manufacturing of ONS-5010:

> We are working with FujiFilm Diosynth Biotechnologies, or Fuji, and Ajinomoto Bio-pharma Services, or AjiBio, ***to provide product manufacturing in current Good Manufacturing Practices, or cGMP, manufacturing facilities***. We have also executed a supply agreement for a best-in-class pre-filled ophthalmic syringe, which we believe will provide both ease-of-use for clinicians and add to ONS-5010's safety profile over the current unapproved therapies that have caused problems related to syringe malfunction, contamination, etc. We will screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements as needed.

38. Again, on January 25, 2022, Defendants represented to investors that "[t]he past twelve months have been ***truly transformational***" for the Company, and that "[b]uilding off of that momentum," Outlook had progressed toward the submission of its BLA for ONS-5010. Regarding ONS-5010 and its commercial prospects, Defendants stated that:

> Now more than ever, we believe that ONS-5010 has the opportunity to address a significant unmet need among the retina community and the potential to provide physicians with a safe, effective, and FDA-approved version of bevacizumab that meets standards required for ophthalmic injections. With the potential for impactful milestones on the horizon, we believe we are positioning ourselves for success and remain dedicated to advancing this program to unlock the full potential of Outlook Therapeutics.

39. On February 14, 2022, Outlook filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for its fiscal first quarter ended December 31, 2021 (the "1Q22 10-Q"). With respect to ONS-5010, in addition to substantively the same statements as referenced in ¶ 37, Defendants stated:

> Our clinical program for ONS-5010 in wet AMD involves three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. ***We reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study, in August 2020.*** NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 (bevacizumab-vikg) to ranibizumab (LUCENTIS). ***The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters BCVA was met and was both highly statistically significant and clinically relevant***.… NORSE THREE is an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 are available for the initial ONS-5010 BLA submission with the FDA. In March 2021 we reported that the results from NORSE THREE provided a positive safety profile for ONS-5010.

40. On March 31, 2022, Outlook announced that it had submitted to the FDA the BLA for ONS-5010 as a treatment for wet AMD. In the press release

announcing the BLA submission, Defendants touted "[t]he ***significant efficacy results*** we are submitting from our NORSE TWO Phase 3 pivotal trial," which "demonstrated the one-, two- and three-line visual acuity responders one would hope for in a pivotal wet AMD trial."

41. Thereafter, in a press release announcing the Company's financial results for the second quarter of fiscal 2022, issued on May 13, 2022, Defendants continued to heighten market expectations regarding ONS-5010, advising investors that "we are ramping up our pre-commercial launch activities." The press release further represented that "we have continued to add to the expertise of our commercial team to build momentum among partners, payors and the retina community. ***We are focused on positioning ourselves to unlock the full potential of ONS-5010***," which included "best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance, and with drug product manufacturer Aji Biopharma Services for finished drug product." Moreover, according to the announcement, Outlook was "actively building out its distribution and commercial team structures."

42. Also on May 13, 2022, Outlook filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for its fiscal first quarter ended March 31, 2022 (the "2Q22 10-Q"). The 2Q22 10-Q contained substantively the same statements as contained in the 1Q22 10-Q, referenced in ¶ 39, *supra*.

43. Investors first began to learn the truth regarding Outlook and its clinical trial for ONS-5010 on May 31, 2022, when the Company announced that it had voluntarily withdrawn the BLA for ONS-5010 in order to provide additional information requested by the FDA. Outlook acknowledged that it was "actively working to respond to the FDA's request" and that it planned to resubmit a "revised BLA" later in the year. In response to this news, Outlook shares fell nearly 32%, or $0.54 per share, from a closing price of $1.69 per share on May 27, 2022 to a closing price of $1.15 on May 31, 2022, the next trading day.

44. In the same press release on May 31, 2022, despite disclosing the withdrawal of the ONS-5010 BLA, Defendants continued to convey optimism to investors. The release stated that "***[w]e remain confident*** in ONS-5010," and touted the potential of the drug "to be the first FDA-approved ophthalmic formulation of bevacizumab that avoids the public health risk to patients of off-label treatment of bevacizumab that was never approved for any ophthalmic indications."

45. On August 10, 2022, Outlook filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for its fiscal first quarter ended June 30, 2022 (the "3Q22 10-Q"). With respect to ONS-5010, the 3Q22 10-Q contained substantively the same statements as contained in the 1Q22 10-Q, referenced in ¶¶ 37, 39, *supra*.

46. On August 30, 2022, the Company announced that, following receipt of further correspondence from the FDA, having "working diligently to provide the additional required information" and "to address requests from the [FDA]," it had resubmitted the BLA for ONS-5010. In that announcement, Defendants stated that "[w]e believe that this re-submission addresses each of the comments and recommendations from the [FDA], and we are confident in the revised BLA application." That press release touted yet again the results of its clinical trial, stating, "[o]ur NORSE TWO pivotal trial for ONS-5010 showed ***compelling efficacy and clinical relevance coupled with a robust safety profile***, and we are confident that our investigational drug, if approved, will be a valuable therapeutic option to treat retina diseases."

47. On December 29, 2022, Outlook issued a press release during pre-market hours announcing the Company's financial results for its fiscal year 2022 and providing a corporate update. This press release quoted Defendant Trenary, who stated, in relevant part:

> Our fiscal year 2022 laid a solid foundation for what we believe will be a transformational 2023. We are driving our commercialization planning towards expected launch with the accepted FDA filing of our BLA for ONS-5010 and PDUFA date set for August 29, 2023 . . . . We believe that ONS-5010 has the potential to be a game-changer for patients and physicians in the retina community, and we now have the necessary capital to support these efforts.

48. With respect to Outlook's pre-launch commercial planning for ONS-5010, including the Company's purported "best-in-class partnerships" for drug substance and manufacturing, the December 29, 2022 press release stated, in relevant part:

> In anticipation of potential FDA marketing approval in 2023, Outlook Therapeutics has begun commercial launch planning, including best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance, and with drug product manufacturer Aji Bio-pharma Services for the finished drug product.
>
> Outlook Therapeutics is actively building out its sales and commercial team, and in September 2022, Outlook Therapeutics entered into a strategic commercialization agreement with AmerisourceBergen in preparation for the anticipated commercial launch in the United States of ONS-5010 . . . . To bring ONS-5010 to market in a way that benefits all stakeholders – patients, clinicians, and payors – Outlook Therapeutics has also been in collaborative discussions with payors and the retina community.

49. Also on December 29, 2022, Outlook filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operational results for its fiscal fourth quarter and year ended September 30, 2022 (the "2022 10-K"). With respect to the ONS-5010 BLA and its regulatory history, including the Company's purported supplementation of additional information necessary to re-submit the ONS-5010 BLA, the 2022 10-K stated, *inter alia*:

> Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. In March 2022, we submitted a [BLA] with the FDA for ONS-5010 (LYTENAVA (bevacizumab-vikg)), an investigational ophthalmic

> formulation of bevacizumab, which we have developed to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. ***In May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We resubmitted the BLA to the FDA for ONS-5010 on August 30, 2022***, and in October 2022, we received confirmation from the FDA that our BLA has been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA.

50. With respect to the purported "clinically impactful" and "highly statistically significant and clinically relevant" data that supported the ONS-5010 BLA, the 2022 10-K stated, *inter alia*:

> Our BLA registration program for ONS-5010 in wet AMD involved three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for our clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019. ***In August 2020, we reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE***, a clinical experience study. NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 (bevacizumab-vikg) to ranibizumab (LUCENTIS). ***The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in Best Corrected Visual Acuity, or BCVA, score was met and was both highly statistically significant and clinically relevant*** . . . . NORSE THREE is an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 were available for the initial ONS-5010 BLA submission with the FDA. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010.

51. The 2022 10-K also asserted that Outlook had worked closely with regulatory authorities to "establish clear guidelines" and a "well-defined regulatory pathway" for ONS-5010's regulatory approval. In describing how Outlook was purportedly "engaging with regulatory agencies to establish clear guidelines for potential approval," Defendants stated:

> We have continued our approach to work closely with regulatory authorities to develop and conduct clinical trials that we believe will appropriately support approval of our product candidates if our clinical trials are successful. As an ophthalmic formulation of bevacizumab, we believe ONS-5010 has a well-defined regulatory pathway.

52. With respect to the purported "current Good Manufacturing Practices" ("cGMP") that Outlook employed for ONS-5010, the 2022 10-K stated, in relevant part, that "[w]e are working with FujiFilm Diosynth Biotechnologies, or Fuji, and Ajinomoto Bio-pharma Services, or AjiBio, to provide product manufacturing in [cGMP] manufacturing facilities" and that "[w]e will screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements as needed."

53. The 2022 10-K also purported to warn investors of risks related to the proper manufacturing of ONS-5010 and its manufacturing partners' compliance with cGMP. Providing generic, catch-all language not at all tailored to actual known risks regarding Outlook's and/or its manufacturer's deficient CMC, as well as other

manufacturing issues for ONS-5010, which remained unresolved at the time the ONS-5010 BLA was re-submitted to the FDA, Defendants stated, in relevant part:

> Reliance on third-party manufacturers entails . . . risks, including reliance on the third party for regulatory compliance and quality assurance . . . . In addition, third-party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the United States. Our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in [*inter alia*] . . . delays . . . of approvals . . . . Any failure . . . to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

54. Appended as an exhibit to the 2022 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendants Trenary and Kenyon "certifie[d] that the [2022 10-K] fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the [Exchange Act], as amended, and that information contained in the [2022 10-K] fairly presents in all material respects the financial condition and results of operations of the [Company]."

55. On February 14, 2023, Outlook issued a press release announcing the Company's financial results for the first quarter of its fiscal year 2023 and providing a corporate update. This press release quoted Defendant Trenary, who stated, in relevant part:

> Our first fiscal quarter of 2023 continued to demonstrate solid execution toward the potential commercialization of ONS-5010. With the accepted FDA filing of our BLA for ONS-5010 and PDUFA date set for August 29, 2023 ... we are well on our way toward our goal of becoming a commercial-stage company....

> Looking ahead, we remain focused on execution and positioning ourselves for a commercial launch of ONS-5010 to enhance the standard of care in the retinal anti-VEGF space.

56. The February 14, 2023 press release also contained substantively the same statements as referenced in ¶¶ 47-48, 49-52, *supra*, regarding Outlook's pre-launch commercial planning for ONS-5010, including the Company's purported "best-in-class partnerships" for drug substance and manufacturing, as well as the purportedly "clinically impactful" results of the NORSE trials.

57. Also on February 14, 2023, Outlook filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for its first fiscal quarter ended December 31, 2022 (the "1Q23 10-Q"). With respect to the ONS-5010 BLA and its regulatory history, including the Company's purported confirmation of additional information necessary to re-submit the ONS-5010 BLA, the 1Q23 10-Q stated, *inter alia*:

> Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. In March 2022, we submitted a BLA with the FDA for ONS-5010 (LYTENAVA (bevacizumab-vikg)), an investigational ophthalmic formulation of bevacizumab, which we have developed to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. ***In May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. Following receipt of further correspondence from the FDA, we confirmed the additional information necessary to re-submit the BLA for ONS-5010 and resubmitted the BLA in August 2022.*** In October 2022, we received confirmation from the FDA that

> our BLA has been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA.

58. With respect to the purported "clinically impactful" and "highly statistically significant and clinically relevant" data supporting the ONS-5010 BLA, the 1Q23 10-Q stated, in relevant part:

> Our BLA . . . registration program for ONS-5010 in wet AMD involved three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for our clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019. ***In August 2020, we reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE***, a clinical experience study. NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 (bevacizumab-vikg) to ranibizumab (LUCENTIS). ***The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in Best Corrected Visual Acuity, or BCVA, score was met and was both highly statistically significant and clinically relevant.*** In the intent to treat, or ITT, primary dataset, the percentage of patients who gained at least 15 letters who were treated with ONS-5010, was 41.7%, and the percentage of patients who gained at least 15 letters who were treated with ranibizumab was 23.1% (p = 0.0052). ***The primary endpoint was also statistically significant and clinically relevant in the secondary per protocol, or PP, dataset*** (p = 0.04) where the percentages were almost identical, at 41.0% with ONS-5010, and 24.7% with ranibizumab. ***The key secondary endpoint BCVA score change from baseline to month 11 in the primary ITT dataset was also highly statistically significant and clinically relevant*** (p = 0.0043). A mean change of 11.2 letters in BCVA score was observed with ONS-5010, and with ranibizumab the mean change was 5.8

> letters. ***The results were also statistically significant in the secondary PP dataset*** (p = 0.05) with a mean change with ONS-5010 of 11.1 letters versus 7.0 letters with ranibizumab. ***Results were also positive for the remaining NORSE TWO secondary endpoints*** with 56.5% (p = 0.0016) of ONS-5010 subjects gaining ≥ 10 letters of vision and 68.5% (p = 0.0116) of ONS-5010 subjects gaining ≥ 5 letters of vision. NORSE THREE is an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 were available for the initial ONS-5010 BLA submission with the FDA. In March 2021, we reported that the ***results from NORSE THREE showed a positive safety profile for ONS-5010***.

59. Appended as an exhibit to the 1Q23 10-Q were substantively the same SOX certifications as referenced in ¶ 54, *supra*, signed by Defendants Trenary and Kenyon.

60. On May 15, 2023, Outlook issued a press release announcing the Company's financial results for the second quarter of its fiscal year 2023 and providing a corporate update. This press release quoted Defendant Trenary, who touted the Company's progress with FDA approval of ONS-5010, stating, in relevant part:

> We continue to make significant progress in our pre-launch activities as we approach our PDUFA goal date [for the ONS-5010 BLA] set for August 29, 2023, just three short months away. These initiatives are focused on positioning Outlook Therapeutics as an upcoming leader in the anti-VEGF space by meeting FDA requirements for an ophthalmic approval . . . . We believe ONS-5010, if approved, has the potential to be the standard of care in the retinal anti-VEGF space and look forward to potentially bringing to market the first FDA-approved ophthalmic formulation of bevacizumab[.]

61. With respect to the purported "statistically significant" clinical data supporting the ONS-5010 BLA, the May 15, 2023 press release stated, in relevant part:

> In the NORSE TWO Phase 3 clinical trial, which compared ONS-5010 (dosed monthly) with LUCENTIS (using the PIER dosing regimen), ***ONS-5010 showed significantly higher results in improving BCVA*** by ≥ 15 letters from baseline at 11 months (41.7% compared to 23.1% in LUCENTIS group, p = 0.0052). ***Patients receiving ONS-5010 also demonstrated statistically significant mean change in BCVA*** of 11.2 letters compared to 5.8 letters in the control arm (p = 0.0043). Additionally, the majority of ONS-5010 subjects maintained or gained BCVA during the study (defined as change from baseline in BCVA ≥ 0), with at least 80% of ONS-5010 subjects maintaining BCVA each month.

62. The May 15, 2023 press release also contained substantively the same statements as referenced in ¶¶ 47-48, 49-52, *supra*, regarding Outlook's pre-launch commercial planning for ONS-5010, including the Company's purported "best-in-class partnerships" for drug substance and manufacturing, as well as the purportedly "clinically impactful" results of the NORSE trials.

63. Also on May 15, 2023, Outlook filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for its second fiscal quarter ended March 31, 2023 (the "2Q23 10-Q"). The 2Q23 10-Q contained the same statements as referenced in ¶¶ 47-52, *supra*, regarding the ONS-5010 BLA, its regulatory history, including the Company's purported confirmation of additional information necessary to re-submit the ONS-5010 BLA, and the

purported "clinically impactful" and "highly statistically significant and clinically relevant" data used to support that BLA.

64. Appended as an exhibit to the 2Q23 10-Q were substantively the same SOX certifications as referenced in ¶ 54, *supra*, signed by the Individual Defendants.

65. On August 14, 2023, Outlook issued a press release announcing the Company's financial results for the third quarter of its fiscal year 2023 and reiterating key anticipated near-term milestones. This press release quoted Defendant Trenary, who stated:

> We continue to be focused on our pre-launch activities and positioning for Outlook Therapeutics as an innovative leader in the anti-VEGF space. ***By meeting strict FDA requirements for an ophthalmic approved formulation of bevacizumab, we believe we can enhance the standard of care.*** If we achieve FDA approval, it will be the catalyst to transform Outlook Therapeutics into a commercial-stage company.

66. With respect to the purported "statistically significant" clinical data supporting the ONS-5010 BLA, the August 14, 2023 press release stated, in relevant part:

> In the NORSE TWO Phase 3 clinical trial, which compared ONS-5010 (dosed monthly) with LUCENTIS (using the PIER dosing regimen of 3 consecutive months of loading doses followed by 2 more doses separated by 3 months each), ***ONS-5010 consistently improved BCVA*** by ≥ 15 letters from baseline to 11 months (41.7% compared to 23.1% in LUCENTIS group, p = 0.0052). ***Patients receiving ONS-5010 also demonstrated statistically significant mean change in BCVA*** of 11.2 letters compared to 5.8 letters in the control arm (p = 0.0043). Additionally, the majority of ONS-5010 subjects maintained or gained BCVA during the study (defined as

change from baseline in BCVA ≥ 0), with at least 80% of ONS-5010 subjects gaining or maintaining BCVA each month.

67. The August 14, 2023 press release also contained substantively the same statements as referenced in ¶¶ 47-48, 49-52, *supra*, regarding Outlook's pre-launch commercial planning for ONS-5010, including the Company's purported "best-in-class partnerships" for drug substance and manufacturing, as well as the purportedly "clinically impactful" results from the NORSE trials.

68. Also on August 14, 2023, Outlook filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operational results for its third fiscal quarter ended June 30, 2023 (the "3Q23 10-Q"). The 3Q23 10-Q contained substantively the same statements as referenced in ¶¶ 47-52, *supra*, regarding the ONS-5010 BLA, its regulatory history, including the Company's purported confirmation of additional information necessary to re-submit the ONS 5010 BLA, and the purported "clinically impactful" and "highly statistically significant and clinically relevant" data used to support that BLA.

69. Appended as an exhibit to the 3Q23 10-Q were substantively the same SOX certifications as referenced in ¶ 54, *supra*, signed by the Individual Defendants.

70. The statements referenced in ¶¶ 27-69, *supra*, were materially false and misleading and/or failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) there was a lack of substantial

evidence supporting ONS-5010 as a treatment for wet AMD; (ii) Outlook and/or its manufacturing partner had deficient CMC and other manufacturing issues for ONS-5010, which remained unresolved at the time the ONS-5010 BLA was re-submitted to the FDA; (iii) as a result of all the foregoing, the FDA was unlikely to approve the ONS-5010 BLA in its present form; (iv) accordingly, ONS-5010's regulatory and commercial prospects were overstated; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Full Truth Is Disclosed

71. On August 30, 2023, during pre-market hours, Outlook issued a press release announcing that the FDA had issued a CRL to the ONS-5010 BLA and could not approve the ONS-5010 BLA during the present review cycle because of unresolved CMC and manufacturing site inspection issues, as well as "a lack of substantial evidence." Specifically, that press release stated, in relevant part:

> [T]he U.S. [FDA] has issued a CRL to the Company's BLA for ONS-5010, an investigational ophthalmic formulation of bevacizumab under development to treat wet AMD. While the FDA acknowledged the NORSE TWO pivotal trial met its safety and efficacy endpoints, ***the Agency concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence***.
>
> "We continue to believe in the public health need to provide the retina community with an FDA-approved bevacizumab treatment option for wet AMD. We will request a formal meeting as soon as possible with the FDA to further understand the BLA deficiencies and how best to resolve them. Following this meeting with the FDA,

> the Company will be able to discuss next steps and the expected timing for resolution," said Russell Trenary, President and CEO of Outlook Therapeutics.

72. On this news, Outlook's stock price fell $1.141 per share, or 80.92%, to close at $0.269 per share on August 30, 2023.

73. The financial and pharmaceutical media reacted with surprise and concern. In an article entitled "FDA turns down Outlook's ophthalmic version of Roche's Avastin over manufacturing, data shortfalls," published on August 30, 2023, on *Fierce Pharma*, an online publication that covers pharmaceuticals and drug development, Angus Liu wrote that FDA approval of the ONS-5010 BLA "was largely expected by market watchers ***given existing knowledge*** and the long history of off-label use of [Roche-manufactured] Avastin [of which ONS-5010 was to be a reformulation] in eye diseases. Instead ***the FDA found several problems with Outlook's application despite the package boasting a positive pivotal trial***." The article further observed that, "[i]n the complete response letter to Outlook, ***the FDA flagged several chemistry, manufacturing and controls (CMC) issues, observations from pre-approval manufacturing inspections, and perhaps most damning, the need for further confirmatory clinical evidence***…." Liu also commented on the manufacturers, both of whom had been referenced by Defendants in Outlook's public statements: "Outlook has hired Fujifilm Diosynth Biotechnologies and Ajinomoto Biopharma Services to help make its bevacizumab

reformulation. Neither company responded Fierce Pharma's request for comment by publication time."

74. Likewise, an article published on August 30, 2023 on *Pharmaceutical Technology*, entitled "FDA shuns Outlook Therapeutics with wet AMD drug BLA rejection," characterized the Company's position vis-à-vis ONS-5010 as "bleak." Noting that the market for wet AMD drugs was "crowded" – it included Regeneron's Elyea (afibercept), Roche's Lucentis (ranibizumab), and biosimilar versions of Roche's Avastin (bevacizumab) – the article emphasized Defendants' motivations to get ONS-5010 approved and up and running: a GlobalData consensus estimated that ONS-5010 could yield revenues of ***nearly $1 billion*** in 2029.

75. A report published on *Bloomberg* on August 30, 2023 by analysts Bre Bradham, Ilya Banares, and Jameelah Robinson reported on the more than 80% plunge in Outlook's stock price, noting that Cantor Fitzgerald analyst Kristen Kluska had written that "the selloff comes as ***investors were mostly expecting the drug to be approved***." According to Kluska, "[t]he bottom line is that we got the call wrong, and believe there are several significant concerns listed in [Outlook's August 30, 2023 press release] looking ahead to potential regulatory action with Lytenava [ONS-5010]."

76. The following day, August 31, 2023, analyst H.C. Wainwright & Co. downgraded Outlook's shares from BUY to NEUTRAL, with a price target of $1.00. The analyst indicated it was "disappointed" by the announcement of the CRL.

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

Post-Class Period Developments

78. Approximately two months after the August 30, 2023 disclosures, Outlook provided an update on its meetings with the FDA regarding the ONS-5010 BLA. On November 2, 2023, the Company issued a press release stating that, having completed its meetings with the FDA to discuss the CRL, the FDA had advised the Company that "an additional adequate and well-controlled clinical trial would be required for the approval of ONS-5010 for the treatment of wet AMD." Further, according to the press release, Outlook and the FDA had agreed upon "a clinical trial design that would most likely allow for the resubmission of the ONS-5010 BLA as early as the end of calendar year 2024." Also, the FDA and Outlook had "agreed on the approaches needed to resolve the CMC comments in the CRL."

79. Then, in a Form 8-K filed with the SEC on December 6, 2023, Outlook announced a "strategic organizational realignment" geared toward the "regulatory and commercial priorities" associated with ONS-5010. As part of that realignment,

Defendant Dagnon would no longer serve as Outlook's COO or as any executive officer of the Company.

SCIENTER ALLEGATIONS

80. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

81. 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 those who purchased or otherwise acquired Outlook securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

82. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Outlook securities were actively traded on the 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 or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Outlook or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

83. 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.

84. 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.

85. 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 federal securities laws were 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, operations and management of Outlook;

- whether the Individual Defendants caused Outlook to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Outlook 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.

86. 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.

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

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Outlook securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Outlook securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

88. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

89. 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, 92 S. Ct. 2430 (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
(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

90. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

91. This Count is asserted against Defendants and 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.

92. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and 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; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Outlook securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Outlook securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

93. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Outlook

securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Outlook's finances and business prospects.

94. By virtue of their positions at Outlook, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

95. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Outlook, the Individual Defendants had knowledge of the details of Outlook's internal affairs.

96. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the

content of the statements of Outlook. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Outlook's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Outlook securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Outlook's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Outlook securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

97. During the Class Period, Outlook securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Outlook securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at

the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Outlook securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Outlook securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

98. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

99. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

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

100. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

101. During the Class Period, the Individual Defendants participated in the operation and management of Outlook, and conducted and participated, directly and indirectly, in the conduct of Outlook's business affairs. Because of their senior

positions, they knew the adverse non-public information about Outlook's misstatement of income and expenses and false financial statements.

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

103. 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 Outlook disseminated in the marketplace during the Class Period concerning Outlook's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Outlook to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Outlook 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 Outlook securities.

104. Each of the Individual Defendants, therefore, acted as a controlling person of Outlook. By reason of their senior management positions and/or being directors of Outlook, each of the Individual Defendants had the power to direct the

actions of, and exercised the same to cause, Outlook to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Outlook and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

105. 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 Outlook.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: Respectfully submitted,