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, and LAWRENCE A. KENYON, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, 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 the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") 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

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 December 29, 2022 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. In August 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, among other things, "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 (the "ONS-5010 BLA"), which the Company planned to submit to the FDA in the first quarter of 2022.

4. In March 2022, Outlook announced that it had submitted the ONS-5010 BLA to the FDA. Thereafter, in May 2022, the Company voluntarily withdrew the ONS-5010 BLA to provide additional information requested by the FDA. Following receipt of further correspondence from the FDA, the Company purportedly "confirmed the additional information necessary to re-submit the BLA for ONS-5010" and resubmitted the BLA in August 2022.

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 partner had deficient

chemistry manufacturing and controls ("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.

6. On August 30, 2023, Outlook issued a press release announcing that the FDA had issued a complete response letter ("CRL") to the ONS-5010 BLA. 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%, 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 ("NASDAQ") under the ticker symbol "OTLK".

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

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

17. Defendants Trenary and Kenyon are referred to herein collectively as the "Individual Defendants".

18. 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 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.

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

SUBSTANTIVE ALLEGATIONS

Background

20. 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.

21. In August 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, among other things, "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, which the Company planned to submit to the FDA in the first quarter of 2022.

22. In March 2022, Outlook announced that it had submitted the ONS-5010 BLA to the FDA. Thereafter, in May 2022, the Company voluntarily withdrew the ONS-5010 BLA to provide additional information requested by the FDA. Following receipt of further correspondence from the FDA, the Company purportedly

"confirmed the additional information necessary to re-submit the BLA for ONS-5010" and resubmitted the BLA in August 2022.

Materially False and Misleading Statements Issued During the Class Period

23. The Class Period begins on December 29, 2022, when 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 (the "FY22 Press Release"). The FY22 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.

24. 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 FY 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.

25. 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 re-submitted 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.

(Emphasis added.)

26. 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.

(Emphases added.)

27. 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, stating, in relevant part:

> - ***Engaging with regulatory agencies to establish clear guidelines for potential approval.*** 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.

(Emphasis in original.)

28. 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."

29. 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, stating, 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.

Plainly, the foregoing risk warning was a generic, catch-all provision that was not tailored to Outlook's actual known risks regarding its 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.

30. Appended as an exhibit to the 2022 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein the Individual Defendants "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]."

31. 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 (the "1Q23 Press Release"). The 1Q23 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.

32. The 1Q23 Press Release also contained substantively the same statements as referenced in ¶ 24, *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.

33. 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.

(Emphasis added.)

34. 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.

(Emphases added.)

35. Appended as an exhibit to the 1Q23 10-Q were substantively the same SOX certifications as referenced in ¶ 30, *supra*, signed by the Individual Defendants.

36. 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 (the "2Q23 Press Release"). The 2Q23 Press Release quoted Defendant Trenary, who stated, 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[.]

37. With respect to the purported "statistically significant" clinical data supporting the ONS-5010 BLA, the 2Q23 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.

(Emphases added.)

38. The 2Q23 Press Release also contained substantively the same statements as referenced in ¶ 24, *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.

39. 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 ¶¶ 33-34, *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.

40. Appended as an exhibit to the 2Q23 10-Q were substantively the same SOX certifications as referenced in ¶ 30, *supra*, signed by the Individual Defendants.

41. 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 (the "3Q23 Press Release"). The 3Q23 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.

(Emphasis added.)

42. With respect to the purported "statistically significant" clinical data supporting the ONS-5010 BLA, the 3Q23 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.

(Emphases added.)

43. The 3Q23 Press Release also contained substantively the same statements as referenced in ¶ 24, *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.

44. 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 ¶¶ 33-34, *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.

45. Appended as an exhibit to the 3Q23 10-Q were substantively the same SOX certifications as referenced in ¶ 30, *supra*, signed by the Individual Defendants.

46. The statements referenced in ¶¶ 23-45 were materially false and misleading because Defendants made false and/or misleading statements, as well as 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 Truth Emerges

47. 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.

(Emphasis added.)

48. 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.

49. 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.

SCIENTER ALLEGATIONS

50. 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

51. 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.

52. 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.

53. 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.

54. 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.

55. 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.

56. 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.

57. 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.

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

59. 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)

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

61. 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.

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

67. 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.

68. 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.

69. 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)

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

71. 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.

72. 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.

73. 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.

74. 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.

75. 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:

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