

**SUPERIOR COURT OF THE STATE OF NEW JERSEY
FOR THE COUNTY OF SOMERSET**

_____, Individually and On Behalf
of All Others Similarly Situated,

Plaintiff,

v.

OSMOTICA PHARMACEUTICALS PLC,
BRIAN MARKISON, ANDREW
EINHORN, DAVID BURGSTAHLER,
SRIRAM VENKATARAMAN, CARLOS
SIELECKI, JUAN VERGEZ, JEFFERIES,
LLC, BARCLAYS CAPITAL INC., RBC
CAPITAL MARKETS, LLC, and WELLS
FARGO SECURITIES, LLC,

Defendants.

Case No.: DRAFT

**CLASS ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

JURY TRIAL DEMANDED

Law Offices of Howard G. Smith

Plaintiff _____ (“Plaintiff”), by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff’s information and belief is based upon, among other things, his counsel’s investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Osmotica Pharmaceuticals plc (“Osmotica” or the “Company”) with the United States Securities and Exchange Commission (“SEC”); (b) review and analysis of press releases and media reports issued by and disseminated by Osmotica; and (c) review of other publicly available information concerning Osmotica.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired the common stock of Osmotica pursuant and/or traceable to the Company’s false and/or misleading registration statement and prospectus (collectively, the “Registration Statement”) issued in connection with the Company’s October 18, 2018 initial public offering (“IPO” or the “Offering”), seeking to pursue remedies under Sections 11, 12 and 15 of the Securities Act of 1933 (the “Securities Act”).

2. Osmotica is a biopharmaceutical company with two lead product candidates: Ontinua ER to alleviate spasticity resulting from multiple sclerosis and RVL-1201 to treat blepharoptosis.

3. On October 19, 2018, the Company filed with the SEC its IPO prospectus, which forms part of the Registration Statement. In the IPO, the Company sold 7,647,500 shares of common stock at a price of \$7.00 per share. The Company received proceeds of approximately \$58.1 million from the IPO, net of underwriting discounts and commissions. The proceeds from the IPO were

purportedly to be used to repay portions of certain loans, as well as working capital and other general corporate purposes.

4. On March 27, 2019, after the market closed, Osmotica announced results from the second Phase III trial for Ontinua ER and reported that the drug did not demonstrate superiority to a placebo.

5. On March 28, 2019, Osmotica's share price closed at \$4.00 per share, which was a decline of \$3.00, or approximately 43%, from the IPO price of \$7.00 per share.

6. The Registration Statement was materially false and misleading and omitted to state: (1) that positive results for the initial Phase III trial for Ontinua ER were generated by irregularities and deficiencies in the Company's good clinical practices; (2) that the Company's second Phase III trial for Ontinua ER was unlikely to replicate the initial trial's positive results; (3) that Ontinua ER was less effective than existing treatments for spasticity resulting from multiple sclerosis; and (4) that, as a result of the foregoing, Defendants' statements in the Registration Statement regarding Osmotica's business, operations, and prospects, were materially false and/or misleading.

JURISDICTION AND VENUE

7. The claims asserted herein arise under and pursuant to Sections 11, 12 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o). This Court has jurisdiction over the subject matter of this action pursuant to Section 22 of the Securities Act, 15 U.S.C. § 77v, which explicitly states that "[e]xcept as provided in section 16(c), no case arising under this title and brought in any State court of competent jurisdiction shall be removed to any court in the United States." Section 16(c) of the Securities Act refers to "covered class actions," which are defined as lawsuits brought as class actions or brought on behalf of more than fifty persons asserting claims under state or common law. This is an

action asserting federal law claims. Thus, it does not fall within the definition of a “covered class action” under §16(c) and therefore is not removable to federal court under the Securities Litigation Uniform Standards Act of 1998.

8. Each Defendant has sufficient contacts with New Jersey, or otherwise purposefully avails themselves of benefits of New Jersey or has property in New Jersey so as to render the exercise of jurisdiction over each by the New Jersey courts consistent with traditional notions of fair play and substantial justice.

9. This Court has jurisdiction over the subject matter of this action pursuant to Section 22 of the Securities Act (15 U.S.C. § 77v).

10. Venue is proper in this Court pursuant to Section 22 of the Securities Act, 15 U.S.C. § 77v. Many of the violations of law complained of herein occurred in this State and in large part in this County, including the dissemination of the materially false and misleading statements complained of herein into this State and into this County. In addition, many Defendants are residents of, do business in, or maintain offices in, this County.

PARTIES

11. Plaintiff _____ purchased Osmotica securities pursuant and/or traceable to the Registration Statement issued in connection with the Company’s IPO and has been damaged thereby.

12. Defendant Osmotica is incorporated under the laws of Ireland with its principal executive offices located in Bridgewater, New Jersey.

13. Defendant Brian Markison (“Markison”) was, at all relevant times, the Chief Executive Officer and Chairman of the Board of Directors, and signed or authorized the signing of the Company’s Registration Statement filed with the SEC.

14. Defendant Andrew Einhorn (“Einhorn”) was, at all relevant times, the Chief Financial Officer of the Company, and signed or authorized the signing of the Company’s Registration Statement filed with the SEC.

15. Defendant David Burgstahler (“Burgstahler”) was a Director of the Company and signed or authorized the signing of the Company’s Registration Statement filed with the SEC.

16. Defendant Sriram Venkataraman (“Venkataraman”) was a Director of the Company and signed or authorized the signing of the Company’s Registration Statement filed with the SEC.

17. Defendant Carlos Sielecki (“Sielecki”) was a Director of the Company and signed or authorized the signing of the Company’s Registration Statement filed with the SEC.

18. Defendant Juan Vergez (“Vergez”) was a Director of the Company and signed or authorized the signing of the Company’s Registration Statement filed with the SEC.

19. Defendants Markison, Einhorn, Burgstahler, Venkataraman, Sielecki, and Vergez are collectively referred to hereinafter as the “Individual Defendants.”

20. Defendant Jefferies LLC (“Jefferies”) served as an underwriter for the Company’s IPO. In the Offering, Jefferies agreed to purchase 2,327,500 shares of the Company’s common stock, exclusive of the over-allotment option.

21. Defendant Barclays Capital Inc. (“Barclays”) served as an underwriter for the Company’s IPO. In the Offering, Barclays agreed to purchase 1,995,000 shares of the Company’s common stock, exclusive of the over-allotment option.

22. Defendant RBC Capital Markets, LLC (“RBC Capital”) served as an underwriter for the Company’s IPO. In the Offering, RBC Capital agreed to purchase 1,330,000 shares of the Company’s common stock, exclusive of the over-allotment option.

23. Defendant Wells Fargo Securities, LLC (“Wells Fargo”) served as an underwriter for the Company’s IPO. In the Offering, Wells Fargo agreed to purchase 997,500 shares of the Company’s Common stock, exclusive of the over-allotment option.

24. Defendants Jefferies, Barclays, RBC Capital, and Wells Fargo are collectively referred to hereinafter as the “Underwriter Defendants.”

CLASS ACTION ALLEGATIONS

25. Plaintiff brings this action as a class action pursuant to New Jersey Court Rule 4:32-1 on behalf of a Class, consisting of all persons and entities that purchased or otherwise acquired the Common stock of Osmotica pursuant and/or traceable to the Company’s false and/or misleading Registration Statement issued in connection with the Company’s IPO, and who were damaged thereby (the “Class”). Excluded from the Class are Defendants, the officers and directors of the Company or its related entities, 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.

26. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. The Company sold 7,647,500 shares of common stock in the IPO. Moreover, record owners and other members of the Class may be identified from records maintained

by Osmotica 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.

27. 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.

28. 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.

29. 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:

- (a) whether the Securities Act was violated by Defendants' acts as alleged herein;
- (b) whether the Registration Statement and statements made by Defendants to the investing public in connection with the Company's IPO omitted and/or misrepresented material facts about the business, operations, and prospects of Osmotica; and
- (c) to what extent the members of the Class have sustained damages and the proper measure of damages.

30. 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.

SUBSTANTIVE ALLEGATIONS

CLASS ACTION COMPLAINT

Background

31. Osmotica is a biopharmaceutical company with two lead product candidates: Ontinua ER to alleviate spasticity resulting from multiple sclerosis and RVL-1201 to treat blepharoptosis

The Company's False and/or Misleading Registration Statement and Prospectus

32. On October 17, 2018, Osmotica filed its final amendment to the Registration Statement with the SEC on Form S-1/A. The Registration Statement was declared effective the same day.

33. On October 19, 2018, the Company filed with the SEC its IPO prospectus, which forms part of the Registration Statement. In the IPO, the Company sold 7,647,500 shares of common stock at a price of \$7.00 per share. The Company received proceeds of approximately \$58.1 million from the IPO, net of underwriting discounts and commissions. The proceeds from the IPO were purportedly to be used to repay portions of certain loans, as well as working capital and other general corporate purposes.

34. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading, and was not prepared in accordance with the rules and regulations governing its preparation.

35. Under applicable SEC rules and regulations, the Registration Statement was required to disclose known trends, events or uncertainties that were having, and were reasonably likely to have, an impact on the Company's continuing operations.

36. The Registration Statement claimed that the key component of Ontinua ER had been proven to be more effective than existing treatments for the indication:

Therapeutic options for spasticity associated with multiple sclerosis include oral medications such as baclofen, which is the most common first-line treatment option. . . .

Baclofen is the only FDA-approved product that targets the GABA b receptor to treat spasticity. Baclofen is a racemic mixture comprised of an R and an S-isomer. ***Importantly, the R-isomer of baclofen, or arbaclofen, which is the sole constituent of Ontinua ER, has been shown in vivo to be up to 100 times more effective at targeting the GABA b receptor than the S-isomer. Consequently, we believe Ontinua ER may be a more efficacious treatment relative to the existing standard of care.***

(Emphasis added.)

37. The Registration Statement described the clinical trials for Ontinua ER and noted that the initial Phase III trial had achieved statistically significant results:

Clinical Overview

In mid-2017, we initiated our second Phase III clinical trial to evaluate the efficacy of Ontinua ER. We anticipate completing enrollment of the 510-patient trial by the end of 2018. The trial is designed as a double-blind, randomized (1:1:1) study to demonstrate the safety and efficacy of Ontinua ER 40 mg/day and Ontinua ER 80 mg/day versus placebo for treatment of spasticity in patients with multiple sclerosis over a 12-week timeframe. The study's co-primary endpoints are Total Numeric Transformed Modified Ashworth Scale, or TNmAS, in the most affected limb and Clinical Global Impression of Change, or CGIC. We believe that a positive result from this trial, combined with our existing clinical and pre-clinical data package, will enable us to complete the submission of our NDA by the end of 2019. We are also concurrently conducting a long-term safety trial for Ontinua ER which aims to enroll 250 patients. If approved by the FDA, we intend to begin commercialization of Ontinua ER as early as 2020.

In 2014, we completed our initial Phase III clinical trial exploring the efficacy, safety and tolerability of arbaclofen in the treatment of spasticity associated with multiple sclerosis. The multicenter, randomized (1:1:1), double-blind, active and placebo-controlled, 16-week study included 341 patients across three groups: Ontinua ER tablets 40 mg/day, baclofen 80 mg/day and placebo. . . . ***[I]n this Phase III clinical trial, Ontinua ER demonstrated a statistically significant improvement in CGIC when compared to the placebo while baclofen failed to demonstrate a statistically significant improvement in CGIC when compared to the placebo.***

(Emphasis added.)

38. The Registration Statement also stated that there deviations from good clinical practices in conducting the initial Phase III trial:

[T]he FDA requested an independent audit of five of the 35 study sites, which were located in Russia and Ukraine. The audit found numerous irregularities and deviations from good clinical practices, which led to a complete response letter on July 9, 2016. The audit observations were thoroughly investigated, and data were corrected where appropriate. In December 2016, we met with the FDA to discuss the path forward for the application. The FDA indicated that, based on the initial audit findings, it considered the data from the Phase III clinical trial to be insufficient to support a marketing application. Following the meeting, we decided to complete a single additional Phase III clinical trial, which, if successful, we believe would support approval of Ontinua ER.

39. The Registration Statement was materially false and misleading and omitted to state: (1) that positive results for the initial Phase III trial for Ontinua ER were generated by irregularities and deficiencies in the Company's good clinical practices; (2) that the Company's second Phase III trial for Ontinua ER was unlikely to replicate the initial trial's positive results; (3) that Ontinua ER was less effective than existing treatments for spasticity resulting from multiple sclerosis; and (4) that, as a result of the foregoing, Defendants' statements in the Registration Statement regarding Osmotica's business, operations, and prospects, were materially false and/or misleading.

The Subsequent Disclosure

40. On March 27, 2019, after the market closed, Osmotica announced results from the second Phase III trial for Ontinua ER and reported that the drug did not demonstrate superiority to a placebo. In a press release, the Company stated:

The co-primary efficacy measures assessed in this study were CGIC (Clinical Global Impression of Change) and the change from baseline in TNmAS (the Total Numeric modified Ashworth Scale). The CGIC is a generalized global assessment of patient well-being, and TNmAS is a more objective measure of muscular spasticity. The change from baseline through day 84 of treatment was assessed for both endpoints.

Arbaclofen did not demonstrate superiority to placebo as measured by the CGIC; however, a statistically significant improvement in spasticity relative to placebo was demonstrated as measured by the TNmAS ($p=0.0482$ and 0.0118) for 40 mg and 80 mg per day, respectively. Upon preliminary review, it appears that CGIC failed to

recognize the improvement demonstrated by the TNmAS. However, the CGIC values indicated both treatment groups improved from baseline.

41. On March 28, 2019, Osmotica's share price closed at \$4.00 per share, which was a decline of \$3.00, or approximately 43%, from the IPO price of \$7.00 per share.

FIRST CLAIM
Violation of Section 11 of the Securities Act
(Against All Defendants)

42. Plaintiff repeats and re-alleges each and every allegation contained above.

43. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against all Defendants (the "Section 11 Defendants").

44. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

45. Osmotica is the registrant for the IPO. The Section 11 Defendants named herein were responsible for the contents and dissemination of the Registration Statement.

46. As issuer of the shares, Osmotica is strictly liable to Plaintiff and the Class for the misstatements and omissions.

47. None of the Section 11 Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

48. By reasons of the conduct herein alleged, each Section 11 Defendant violated, and/or controlled a person who violated Section 11 of the Securities Act.

49. Plaintiff acquired Osmotica common stock pursuant and/or traceable to the Registration Statement for the IPO.

50. Plaintiff and the Class have sustained damages. The value of Osmotica Common stock has declined substantially subsequent to and due to Section 11 Defendants violations.

SECOND CLAIM
Violation of Section 12(a)(2) of The Securities Act
(Against All Defendants)

51. Plaintiff repeats and re-alleges each and every allegation contained above, except any allegation of fraud, recklessness or intentional misconduct.

52. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, on behalf of the Class, against all Defendants (the “Section 12 Defendants”).

53. The Section 12 Defendants were sellers, offerors, and/or solicitors of purchasers of Class A common stock offered by Osmotica pursuant to the IPO. The Section 12 Defendants issued, caused to be issued, and/or signed the Registration Statement in connection with the Offering. The Registration Statement was used to induce investors, such as Plaintiff and other members of the Class, to purchase Osmotica securities.

54. The Registration Statement was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

55. The Section 12 Defendants’ actions of solicitation included participating in the preparation of the false and/or misleading Registration Statement.

56. None of the Section 12 Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

57. Plaintiff and other Class members did not know, nor could they have known, of the untruths and/or omissions contained in the Registration Statement.

58. By virtue of the conduct alleged herein, the Section 12 Defendants are liable for the aforesaid wrongful conduct and are liable to Plaintiff and the Class for damages suffered.

THIRD CLAIM
Violation of Section 15 of The Securities Act
(Against the Individual Defendants)

59. Plaintiff repeats and re-alleges each and every allegation contained above.

60. This count is asserted against the Individual Defendants (the “Section 15 Defendants”) and is based upon Section 15 of the Securities Act.

61. The Section 15 Defendants, by virtue of their offices, directorship and specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Osmotica within the meaning of Section 15 of the Securities Act. The Section 15 Defendants had the power and influence and exercised the same to cause Osmotica to engage in the acts described herein.

62. The Section 15 Defendants’ positions made them privy to and provided them with actual knowledge of the material facts concealed from Plaintiff and the Class.

63. By virtue of the conduct alleged herein, the Section 15 Defendants are liable for the aforesaid wrongful conduct and are liable to Plaintiff and the Class for damages suffered.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

CLASS ACTION COMPLAINT

- (a) Determining that this action is a proper class action under New Jersey Court Rule 4:32-1;
- (b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;
- (d) Awarding rescission or a rescissory measure of damages; and
- (e) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: _____, 2019

GLANCY PRONGAY & MURRAY LLP

By: s/ _____ Draft _____

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