Lead Plaintiffs Marsha Gillis, Carl Bayney, and Daniel Rehmsmeyer ("Plaintiffs"), by and through their undersigned attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs’ information and belief is based upon, among other things, counsel’s investigation, which includes, without limitation: (a) a review and analysis of regulatory filings made by QRx Pharma Ltd. ("QRX" or the "Company") with the Australian Securities Exchange ("ASX"); (b) a review and analysis of press releases and media reports issued and disseminated by QRX; (c) a review and analysis of conference calls held by QRX; and (d) a review of other publicly available information concerning QRX.
SUMMARY OF THE ACTION AND OVERVIEW

1. This is a federal securities class action on behalf of all persons or entities who purchased or otherwise acquired QRX American Depository Receipts (“ADR”) between December 6, 2010 and April 23, 2014 inclusive (the “Class Period”). Plaintiffs seek to pursue remedies against QRX and its former Chief Executive Officer (“CEO”) John Holaday (“Holaday”) for violations of §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder.

2. QRX is a specialty pharmaceutical company headquartered in Australia that focuses its research and development on treatments for pain management. QRX’s ADR securities traded over-the-counter in the United States under the ticker symbols “QRXPY”, “QRXPF”, and “QRXPK”. Throughout its history, the Company’s main products have been “Dual Opioid” drugs that combine two different opioid painkillers, morphine and oxycodone, which the Company claims provides effective analgesia while decreasing the frequency and severity of opioid-related side effects. For much of the Company’s history, QRX’s main experimental drug was MoxDuo, a combination of morphine sulfate and oxycodone hydrochloride, which would have been the first combination drug product to contain two active opioid ingredients.

3. Because MoxDuo combined two separate active ingredients, QRX was required to satisfy the FDA’s “combination rule.” Throughout the class period, QRX and Holaday concealed from investors that the FDA made clear in 2004 and consistently thereafter, that in order to satisfy the combination rule, QRX would have to demonstrate that MoxDuo was either more safe or more effective than equivalent doses of Morphine and Oxycodone, i.e., that the whole is better than the sum of its parts. As part of the development process, QRX conducted a trial – Study 008 – that they told investors was designed to satisfy this rule. However, QRX also concealed from the public that the FDA, after reviewing QRX’s proposed protocol for Study 008, had issued a “no agreement
letter” indicating that they did not approve of QRX’s design for Study 008. QRX also failed to disclose that their “combination rule” study could not satisfy the combination rule because it did not demonstrate superiority of MoxDuo against equivalent doses of Morphine and Oxycodone. Despite receiving the no agreement letter, QRX commenced Study 008 on or around November 30, 2009. Despite knowing that the FDA had not signed off on Study 008, and despite the fact that the only study that could conceivably satisfy the superiority requirement of the combination rule, Study 022, was not yet complete, QRX submitted its new drug application for MoxDuo anyway, which included Study 008, in a falsehearted attempt to satisfy the FDA’s combination rule. The FDA set forth the reasons for the rejection in a “complete response letter” that was provided to QRX and Holaday, but not filed publicly, in June 2012, stating that the studies presented thus far do not demonstrate superiority in efficacy or safety. When Holaday later disclosed the complete response letter’s existence on June 27, 2012, he misleadingly omitted the fact that this rejection was based on fundamental disagreements between QRX and the FDA as to the requirements of the combination rule and whether MoxDuo had satisfied the rule, instead, telling the public that MoxDuo was rejected so that QRX could provide additional data. Holaday also did not disclose to the public, that QRX twice appealed the complete response letter to FDA officials, and that those appeals were denied. Instead, Holaday touted his Company’s second submission to the FDA, giving the false impression that QRX had a clear path to getting MoxDuo approved.

4. On April 17, 2014, the Australian Stock Exchange suspended QRX’s trading at the request of QRX, due to pending news from the company. During the trading freeze, the FDA Center for Drug Evaluation and Research released a memorandum (the “FDA Memo”) dated March 26, 2014, recommending denying QRX’s new drug application for MoxDuo. This showed that the FDA regulatory history of MoxDuo that Holaday had previously disclosed to investors was materially misleading. For example, the FDA Memo disclosed that: (i) since 2004, the FDA had
told QRX that in order to satisfy the Combination Rule, QRX must demonstrate that MoxDuo is superior to equivalent doses of morphine and oxycodone alone; (i) the FDA sent the Company the no agreement letter before QRX commenced Study 008 on or around November 30, 2009, stating that it did not agree with QRX’s “proposed efficacy endpoint and statistical approach” for Study 008 in order to obtain approval for MoxDuo; (iii) after the FDA rejected MoxDuo and issued the complete response letter in June 2012, QRX appealed the FDA’s rejection two separate times in 2012, and the FDA denied both appeals; and (iv) MoxDuo clinical studies did not show the safety or efficacy benefits that the FDA had demanded since the beginning of the drug development process, and (v) Study 022 failed to meet its primary endpoint. On April 22, 2014, the FDA’s Anesthetic and Analgesic Drug Products Advisory Committee voted unanimously to recommend against approving MoxDuo.

5. Following disclosure of these previously concealed adverse facts concerning MoxDuo’s regulatory history on April 23, 2014, the price of QRX ADRs dropped over 83%.

6. As a result of Defendant Holaday’s wrongful acts and omissions, QRX ADRs traded at artificially inflated prices during the Class Period, and Plaintiffs and other Class members suffered significant losses and damages.

**JURISDICTION AND VENUE**

7. The claims asserted herein arise under §§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). This Court has jurisdiction over the subject matter of this action pursuant to 28U.S.C. §1331 and §27 of the Exchange Act (15 U.S.C. §78aa).

8. Venue is proper in this District pursuant to 28 U.S.C. §1391(b) and §27(c) of the Exchange Act (15 U.S.C. §78aa(c)). QRX does business in this district and many of the acts complained of herein, including the dissemination of materially false and misleading statements
and reports prepared by or with the participation, acquiescence, encouragement, cooperation, or assistance of Defendant Holaday occurred, at least in part, in this District. The Registration Statement associated with the ADRs was executed in this District. Additionally, the Company has consented to the jurisdiction of this Court in the Deposit Agreement that was entered into by QRX when issuing its ADRs. The Deposit Agreement states, “The Company irrevocably agrees that any legal suit, action or proceeding against the Company brought by the Depositary or any Holder, arising out of or based upon this Deposit Agreement or the transactions contemplated hereby, may be instituted in any state or federal court in New York, New York.”

9. In connection with the acts, transactions, and conduct alleged herein, Defendant Holaday directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

10. Lead Plaintiff Marsha Gillis, as set forth in the certification filed with the Court on August 24, 2015 (Docket No. 18-2), incorporated by reference herein, purchased QRX ADRs during the Class Period and suffered damages as a result of the federal securities law violations and material omissions alleged herein.

11. Lead Plaintiff Cary Bayney, as set forth in the certification filed with the Court on August 24, 2015 (Docket No. 18-2), incorporated by reference herein, purchased QRX ADRs during the Class Period and suffered damages as a result of the federal securities law violations and material omissions alleged herein.

12. Lead Plaintiff Daniel Rehmsmeyer, as set forth in the certification filed with the Court on August 24, 2015 (Docket No. 18-2), incorporated by reference herein, purchased QRX
ADRs during the Class Period and suffered damages as a result of the federal securities law violations and material omissions alleged herein.

13. Defendant Holaday was CEO and managing director of QRX from April 2007 until his resignation on May 3, 2014. Prior to joining QRX, Holaday was founder, Chairman, and Chief Executive officer of CNSCo, a private company that was acquired by QRX. Upon information and belief, Defendant Holaday resides in Bethesda, Maryland.

14. Stayed Defendant QRX is an Australian corporation with principal executive offices located in Victoria, Australia. All claims against QRX are temporarily stayed due to its pending bankruptcy proceeding.

**DEFENDANTS’ FRAUDULENT CONDUCT**

15. QRX’s MoxDuo would have been the first drug to contain two different active opioid ingredients. When a product combines two different drugs, in order to obtain marketing approval, the FDA requires the applicant to satisfy a special requirement called the “combination rule”. The Combination Rule, which appears at 21 CFR 300.50, states, in pertinent part, that “Two or more drugs may be combined in a single dosage form when each component makes a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug.” 21 CFR 300.50. The first part of the combination rule, that each component must make a contribution to the claimed effects of the drug, requires a demonstration that when taken together, the two drugs do not interfere with each other. The second part of the combination rule requires showing that a patient population exists that requires a combination of the two drugs, rather than just one drug or the other, and that such patients can take the drug safely and effectively. This latter requirement can be demonstrated by an applicant if the test shows either improved efficacy, i.e. a synergistic effect, or a better safety profile. Cite, if any.
16. The Company represented that if approved by the FDA, MoxDuo would be prescribed for the treatment of moderate to severe acute pain, which constitutes a $2.5 billion segment of the $8 billion spent annually on prescription opioids in the United States.

17. QRX met with the FDA in January 2004 for a meeting prior to their Investigational New Drug (“IND”) application. An IND is an application that seeks permission to perform clinical, i.e. human, trials. During that meeting, QRX stated to FDA that the rationale for MoxDuo was that QRX believed that the two components of MoxDuo would act synergistically to improve efficacy. QRX confirmed that by synergistically they meant that the whole is greater than the sum of its parts. The FDA made clear to QRX that a synergistic effect was necessary to demonstrate improved efficacy, and that a reduction of dosage in combination cannot be assumed to be of clinical benefit standing alone.

18. In its quest for FDA approval of MoxDuo, QRX conducted a phase 2 study, Study 021, which it completed prior to November 2009, that compared the following treatments: MoxDuo 6/4² mg, MoxDuo 12/8, Morphine 6, Morphine 12, Oxycodone 4, Oxycodone 8. According to the FDA Memo, an analysis of Study 021 showed that MoxDuo was slightly less effective than Morphine or Oxycodone at comparable doses.

19. According to the FDA Memo, in an “end of phase 2” meeting in 2009, QRX asked “about the requirements to support a claim for a synergistic effect on efficacy and about demonstrating improved safety of MoxDuo compared to equianalgesic doses of morphine sulfate

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¹ According to the Background Materials for the Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee, dated April 22, 2014, prepared by Bob Rappaport, the Director of the Division of Anesthesia, Analgesia, and Addiction Products, of the Office of Drug Evaluation II, CDER, FDA (the “FDA Memo”), which is incorporated by reference to the Complaint as if fully set forth herein.

² Following the convention used by the FDA and QRX, references to dosages of MoxDuo, will be in the following form: “MoxDuo x/y” where x = the amount of morphine used and y = the amount of oxycodone used.
and oxycodone hydrochloride alone.” As a result of end of phase 2 meeting, QRX “designed a dedicated safety study intended to show a safety advantage for MoxDuo that would be eligible for inclusion in product labeling.”

20. A SPA is a declaration from the FDA that it approves of the trial’s design, clinical endpoints, and statistical analyses, and that if the study succeeds in achieving the clinical endpoints in accordance with the study protocol, the FDA will approve the drug for sale. A special protocol assessment is binding on the FDA and the drug sponsor. The FDA did not approve the study and refused to enter into an SPA with ARX and instead issued a “no agreement” letter stating that they did not approve of QRX’s “proposed efficacy endpoint and statistical approach” for Study 008. This letter was in Holaday’s personal files and was received by Holaday on June 19, 2009, as indicated in the handwritten note on his copy of the letter. That letter specifically stated that “It is incumbent on you [QRX] to find a patient population that requires the additional benefit that you anticipate from your proposed formulation and demonstrate superiority of the combination over the individual components in an adequate and well-controlled study.” Holaday highlighted this passage. Because Study 008 did not compare MoxDuo with equally potent doses of morphine and oxycodone, it could not possibly demonstrate superiority, as set forth in the FDA Memo.

21. QRX submitted a second request to the FDA for an SPA for Study 008 and received a second “no agreement letter”, which was also in Holaday’s files, and which Holaday dated August 27, 2009. QRX submitted a third request for an SPA and received a letter refusing to provide a third review of Study 008’s protocol. Holaday dated this letter October 5, 2009.

22. Despite the fact that the FDA never approved the protocol and design for Study 008, QRX went forward with Study 008 on or around November 30, 2009. Rather than disclose that it was conducting a study whose design the FDA refused to approve in a series of no agreement letters, QRX instead misrepresented that Study 008 “incorporated input from the FDA
regarding the design and statistical analysis of [the] study”, in the Company’s November 30, 2009 press release announcing the commencement of Study 008.3

23. QRX submitted a “new drug application” (“NDA”) for MoxDuo on August 25, 2011. According to the FDA, “the NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.” In support of its NDA, QRX submitted two Phase II clinical trials, studies 020 and 021, and three Phase III clinical trials, studies 007, 008, and 009. QRX also conducted an additional Phase III study, Study 022, but did not submit the full study report for Study 022 in the original new drug application because the results were not yet completed. Study 022 was the only Phase 3 study that compared MoxDuo with equally potent doses of morphine and oxycodone, and therefore was the only Phase 3 study that could demonstrate superiority and satisfy the combination rule.

24. The FDA did not approve MoxDuo based on the original NDA. Instead, in June of 2012, the FDA issued a “complete response letter” denying the NDA which, according to the FDA Memo made the following findings:

a. “The results of Study 022 alone, which unlike studies 008 and 021 was designed and powered to evaluate the relative safety of Moxduo, morphine and oxycodone, did not replicate the findings for moderate to severe adverse events.” In other words, while earlier studies that were not designed to demonstrate a safety benefit were nonetheless suggestive of a safety benefit, when QRx set out to demonstrate a safety benefit for Study 022, they were unsuccessful in replicating these positive results.

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3 QRX had also previously stated in a press release on August 5, 2008 that the FDA “accepted the design of the proposed combination rule study with minimal modifications.”
b. “Pooled data from Studies 008, 021, and 022 showed that Moxduo-treated subjects did not consistently have a lower incidence of or discontinuations due to nausea, vomiting, or dizziness.”

c. “The text in the proposed label described the respiratory findings of a subset of subjects in the pooled data who were at study centers at lower altitudes. Analysis of the full set of subjects in this same pooled group of studies did not result in the same trend … and the Applicant did not present a convincing rationale for only analyzing data from study sites at lower altitudes.”

d. “a larger proportion of subjects in the Moxduo group were placed on supplemental oxygen, and subjects in the Moxduo group had a higher average number of oxygen desaturations per subject,”

e. “There were no trends in the pooled data favoring Moxduo or the comparators in terms of incidence of common adverse events.”

25. The FDA Memo also revealed that QRX attempted to demonstrate a safety benefit by showing that MoxDuo caused less dizziness, but their analysis only included study centers at lower altitudes. The FDA found that QRX could not present a convincing rationale for this analysis.

26. According to the FDA Memo, the Complete Response Letter also stated that the combination rule requires that MoxDuo demonstrate an efficacy, safety or convenience advantage over individual components at comparable doses, and that QRX failed to do so. “The deficiency cited in the Complete Response letter (CRL) was a lack of evidence that the combination provided any benefit over the individual components and that there was no evidence that there was a patient population that required treatment with MoxDuo. To address this deficiency, the Applicant must provide evidence that MoxDuo either has greater efficacy and, therefore, could result in the need
for a smaller total amount of opioid analgesic, or is safer than comparable doses of morphine and oxycodone.”

27. QRX formally appealed the complete response letter to the FDA office of Drug Evaluation II (“ODEII”) in October of 2012, arguing 1) that MoxDuo should not be subject to the combination rule, and 2) even if MoxDuo is subject to the combination rule, QRX’s studies demonstrated that MoxDuo did satisfy the rule. QRX included a more complete analysis of Study 022 in its submission to ODEII that had only previously been provided to the FDA at an “end of review” meeting but which had not been part of the original application. The director of ODEII, Dr. Curtis Rosebraugh, denied QRX’s appeal, and refused to consider the new information through an appeals process, and instead directed QRX to file a new NDA. QRX then appealed this result to the Office of New Drugs (“OND”) in November of 2012. Dr. Sandra Kweder, the Deputy Director of OND, denied the appeal, fully supporting the FDA’s position.

28. In February of 2013, QRX submitted a response to the Complete Response Letter, indicating that they intended to provide a full Phase 3 study report that would show that MoxDuo offered a safety advantage over morphine and oxycodone. A meeting with the FDA was scheduled for July 17, 2013, but it was cancelled because, in June of 2013, QRX discovered that there was a problem with some of the data, which could not be corrected in time for the meeting. QRX informed the FDA of this on June 19, 2013, and the meeting was cancelled. As to the remaining data that QRX was able to submit, the FDA found that it did not sufficiently demonstrate a safety or efficacy advantage. In August of 2013, the FDA issued a second complete response letter making this clear.

29. After receiving the second Complete Response Letter in August of 2013, QRX submitted another response, which corrected the faulty data discussed in the paragraph above. The FDA concurred that the corrected data was acceptable, but nonetheless, after reviewing all of the
above data, the FDA Memo concluded that MoxDuo does not provide a safety or efficacy benefit over oxycodone and morphine, and should be rejected. It also concluded that Study 022 failed to demonstrate a safety benefit, failed to satisfy its “primary endpoint” and in fact showed numerically inferior results when compared to oxycodone or morphine alone. As a result, on April 22, 2014, the FDA rejected approval of MoxDuo again.

**Materially Misleading Omissions During the Class Period**

30. On December 6, 2010, QRX issued a press release entitled *QRx Pharma Completes Patient Enrolment of Pivotal MoxDuo IR Phase 3 Study*. The press release stated in relevant part:

In April 2010, the company released results from a “combination rule” pivotal study (008) comparing the efficacy and safety profiles of MoxDuo IR against component doses of morphine and oxycodone alone for the management of moderate to severe post-operative pain following bunionectomy surgery. MoxDuo IR not only demonstrated a statistically superior analgesic effect compared to component doses of morphine (p=0.02) and oxycodone (p=0.02) but, also, a favourable side effect profile despite delivering twice the opioid dose of its individual components. This trial met both primary and secondary endpoints. With the successful completion of this knee replacement study (009), the company believes it has met the basic requirements for clinical data to enable NDA filing for MoxDuo IR as targeted for the first half CY2011.

31. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in a no agreement letter, and had specifically required that QRX demonstrate superiority in safety or efficacy for MoxDuo at comparable doses to Morphine and Oxycodone. Thus, Study 008 was irrelevant to FDA approval. Without disclosure that the FDA had already told QRX that Study 008 was categorically insufficient to demonstrate superiority, a requirement for FDA approval, investors would be misled into thinking that approval was a reasonable possibility. It was also misleading to claim that the company met the basic requirements for clinical data to enable NDA filing, because the only study that could possibly satisfy the superiority requirement pursuant to the combination rule, Study 022, was not yet complete.
32. On January 24, 2011, QRX issued a press release entitled *QRx Pharma Initiates Phase 3 Comparative Safety Study of MoxDuo®IR*. The press release stated in relevant part:

Sydney, Australia and Bedminster, NJ (Vocus/PRWEB) January 24, 2011

MoxDuo IR not only demonstrated a statistically superior analgesic effect compared to component doses of morphine (p=0.02) and oxycodone (p=0.02) but, also a favourable side effect profile despite delivering twice the opioid dose of its individual components. With this trial [008], combined with the recently completed total knee replacement study (009 – data to be reported shortly), the Company believes it has met the basic clinical data requirements for NDA filing in Q2 CY2011 as planned.

33. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in the no agreement letter, and because the only study that could possibly satisfy the superiority requirement, Study 022, was not yet complete.

34. On January 27, 2011, QRX issued a press release entitled *Quarterly Operating Update 31 December 2010*. The press release stated in relevant part:

With completion of this Study 009 trial, the company believes it has met the basic clinical data requirements for a New Drug Application (NDA) filing with the United States Food and Drug Administration and is on track for lodgement of a NDA in Q2 CY2011 as planned.

35. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in the no agreement letter, and that therefore QRX had not met the basic clinical data requirements for NDA filing because its’ required “combination rule” study was inadequate.

36. On July 22, 2011, QRX issued a press release entitled *QRx Pharma Announces A$35 Million Capital Raising to Progress MoxDuo Formulations and Support Commercialisation of MoxDuo® IR*. The press release stated in relevant part:

QRx Pharma CEO and Managing Director, Dr. John Holaday commented, "We continue to make significant progress towards commercialising MoxDuo IR,
having just initiated our NDA filing with the FDA.”

37. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in the no agreement letter, and as a result QRX was not making significant progress towards commercializing MoxDuo because the only study that could possibly satisfy the superiority requirement, Study 022, was not complete, and was not included in the NDA.

38. On August 25, 2011, QRX issued a press release entitled QRx Pharma Completes NDA Submission for MoxDuo® IR. The press release stated in relevant part:

   “Since QRxPharma’s initial public offering in 2007, we have strived towards an aggressive commercialisation strategy for MoxDuo – one that streamlined development timelines, was capital efficient, demonstrated clinical advantages of the product, and set the stage for commercial benefits to the company,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “We are pleased to have met this significant NDA milestone in just four years, and look forward to the regulatory approval process that may enable product sales in 2012.”

   This completed NDA submission is based on a full non-clinical, clinical and manufacturing program for MoxDuo IR, and is being filed under 505(b)(2) regulations wherein approval for a new drug may be expedited by citing historical published evidence supporting each of MoxDuo’s already approved components to supplement the data derived from the robust QRxPharma development program. Consistent with the United States Federal Code of Regulations and as agreed with the FDA, the Company previously initiated the NDA review process by filing its completed CMC module in July 2011.

39. The statements in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in a no agreement letter, and that therefore QRX’s submission was not “in agreement with the FDA” and QRX was not following a streamlined and efficient timeline. The statements above are also misleading for failing to disclose that the FDA issued a no agreement letter with respect to Study 008, and therefore QRX would not be able to demonstrate that MoxDuo satisfied the FDA’s combination rule.

40. On June 27, 2012, QRX issued a press release entitled QRxPharma Receives
Complete Response Letter from FDA Regarding MoxDuo® NDA. The press release stated, in pertinent part:

QRxPharma Limited announced today the United States Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the MoxDuo New Drug Application (NDA) for the treatment of moderate to severe acute pain. The Company is presently considering its response to the requests for additional information with regard to the safety and effectiveness of MoxDuo and has been granted a meeting with the FDA to clarify the steps required for approval.

41. The statements in the foregoing paragraph were misleading because stated that the FDA only requested additional information regarding the safety and effectiveness of MoxDuo, when in reality the FDA required that QRX provide evidence that MoxDuo was superior to its components in comparable doses, and found that the data in Study 022 did not do so.

42. On August 20, 2012, QRX issued a press release entitled QRxPharma Reports Productive Meeting with FDA Regarding MOXDUO® NDA. The press release stated, in relevant part:

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the United States Food and Drug Administration (FDA) clarified to Company representatives during a post submission review meeting the steps required for approval of immediate release MOXDUO. The FDA requested further information regarding data filed as part of the MOXDUO New Drug Application (NDA) and additional analysis of trials completed to date, including Study 022 which evaluated oxygen desaturation levels in patients receiving MOXDUO compared to those administered morphine or oxycodone alone at equi-analgesic doses. Oxygen desaturation is a medically important adverse event and a leading cause of death from high doses of opioids. “We were encouraged by our reception at the FDA; the Agency confirmed our Combination Rule Study (Study 008) satisfied efficacy requirements and there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “Additionally, at the FDA’s invitation, we agreed to submit more extensive information on Study 022 and believe the results of this study provide further safety data to support approval of MOXDUO.”

Analysis of Study 022 was completed after the MOXDUO NDA filing in August 2011, although early safety data were included in the 120-day update filed last
December. Accordingly, additional efficacy and safety information from this study was of significant interest to the FDA.

The Company is presently preparing an additional data package for review and is considering further strategies to optimally manage the regulatory process. QRxPharma believes that the review of additional data and subsequent refiling of the NDA could result in a positive decision from the FDA by mid-2013.

43. The statement in the foregoing paragraph was misleading because it omitted to disclose that the “additional steps” required by QRX, as indicated by the FDA for approval were that QRX demonstrate the superiority of MoxDuo to its components at comparable doses and that the data provided to the FDA to date had not done so.

44. On September 21, 2012, QRX issued its 2012 annual report to shareholders. The Annual Report stated, in pertinent part:

The receipt of the Complete Response Letter (CRL) in June 2012 from the US Food and Drug Administration (FDA) in response to our MOXDUO New Drug Application (NDA) was an obvious disappointment. However, we are encouraged by our most recent FDA meeting, a post submission review, in August 2012 during which the Agency confirmed our Combination Rule Study (Study 008) satisfied efficacy requirements and there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA.

45. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in a no agreement letter, and that the Complete Response Letter stated that QRX had not satisfied the FDA’s combination rule.

46. On October 26, 2012, QRX issued a press release entitled Quarterly Operating Update 30 September 2012 that stated, in pertinent part: “at the August 2012 meeting, the FDA confirmed that there were no unexpected or problematic safety issues in any of the studies submitted as part of the NDA.”

47. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in a no agreement letter, that the Complete Response Letter stated that QRX had not satisfied the combination rule, and that QRX
was challenging the FDA’s determinations that MoxDuo must demonstrate superiority in order to satisfy the combination rule and that QRX failed to satisfy the superiority requirements of the combination rule. The statement in the foregoing paragraph was also misleading for failure to disclose that QRX had lost its October 2012 appeal of the June 2012 Complete Response Letter.

48. On November 7, 2012, QRX issued a press release announcing the Company’s annual meeting and containing the Chairman’s Address. *QRxPharma 2012 Annual General Meeting.* The Chairman’s Address stated, in pertinent part:

In June this year we received the disappointing news that the United States Food and Drug Administration (FDA) had issued a Complete Response Letter (CRL), advising that we were not successful with our initial NDA filing in obtaining FDA approval for MOXDUO.

While this turn of events took the Company’s board and management – and shareholders – by surprise, we have since been encouraged by the outcomes of our subsequent dialogue with the FDA.

At a post-submission review meeting with the FDA in August 2012 the steps needed for approval were clarified. Importantly, it was confirmed at this meeting that there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA.

...

Based on the dialogue that has taken place with the FDA, as part of this process, the Board and I remain confident that MOXDUO will receive approval.

49. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in a no agreement letter, that the Complete Response Letter stated that QRX had not satisfied the combination rule, and that to do so QRX was required to demonstrate that MoxDuo show superiority at comparable doses, and that QRX was challenging the FDA’s determinations that MoxDuo must satisfy the combination rule and that QRX failed to satisfy the requirements of the combination rule. The statement in the foregoing paragraph was also misleading for failure to disclose that QRX had lost both appeals of
the June 2012 Complete Response Letter. The statements were also misleading because the FDA Memo stated that study results indicated that MoxDuo’s safety profile was not shown to be superior to morphine and oxycodone.

50. On January 16, 2013, QRX issued a press release entitled QRX Pharma and FDA Establish Path Forward for Resubmission of MoxDuo New Drug Application. This press release stated, in pertinent part:

“Throughout the last several years of FDA interactions on MOXDUO, we have followed the Agency’s recommendations in designing and implementing clinical trials that demonstrated its effectiveness and safety in acute pain patients,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “Recent feedback provided clarity as to the complete response action taken on 25 June, 2012 and, based on the FDA’s advice and recommendations, we are now preparing our revised NDA for submission this quarter.”

51. The statement in the foregoing paragraph was misleading because it omitted to disclose that QRX had gone forward with Study 008 even though the FDA had rejected the protocols for Study 008 in a no agreement letter, that the Complete Response Letter stated that QRX had not satisfied the FDA’s combination rule, and that QRX was challenging the FDA’s determinations that MoxDuo must demonstrate superiority over its components at comparable doses and that QRX failed to satisfy the requirements of the combination rule. The statement in the foregoing paragraph was also misleading for failure to disclose that QRX had lost both appeals of the June 2012 Complete Response Letter.

52. On January 24, 2013, QRX issued a press release entitled Quarterly Operating Update 31 December 2012. The press release stated, in pertinent part:

During the Company’s most recent FDA review meeting, QRxPharma presented a position that although the Combination Rule does not require a demonstration of greater efficacy or safety, the data submitted to date indicate a safety advantage for MOXDUO compared to either morphine or oxycodone alone.

53. The statement in the foregoing paragraph was misleading because it omitted to
disclose that the FDA had rejected the protocols for Study 008 in a no agreement letter, that the Complete Response Letter stated that QRX had not satisfied the combination rule, and that QRX was challenging the FDA’s determinations that MoxDuo must satisfy the combination rule and that QRX failed to satisfy the requirements of the combination rule. The statement in the foregoing paragraph was also misleading for failure to disclose that QRX had lost both appeals of the Complete Response Letter. The statements were also misleading because the FDA Memo stated that study results submitted up to that time indicated that MoxDuo’s safety profile was no better than Morphine or Oxycodone.

54. On February 28, 2013, QRX issued a press release entitled QRxPharma Resubmits MOXDUO® New Drug Application to the FDA. The press release stated, in pertinent part:

“We believe the revised documents effectively address the FDA’s request for additional data resulting from their review of the initial MOXDUO NDA filed in mid-2011,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “To this end, and as recommended by the FDA, a comprehensive analysis of Study 022 was included as part of the resubmitted NDA. This study demonstrated the lower risks of respiratory depression for MOXDUO when compared to either morphine or oxycodone.”

55. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in a no agreement letter, that the Complete Response Letter stated that QRX had not satisfied the combination rule, and that QRX was challenging the FDA’s determinations that MoxDuo must satisfy the combination rule and that QRX failed to satisfy the requirements of the combination rule. The statement in the foregoing paragraph was also misleading for failure to disclose that QRX had lost both appeals of the Complete Response Letter. The statements were also misleading because the FDA Memo stated that study results indicated that MoxDuo’s safety profile was no better than morphine and oxycodone.

56. On April 29, 2013, QRX issued a press release entitled Quarterly Operating Update
31 March 2013. The press release stated, in pertinent part:

During the quarter the Company resubmitted its MOXDUO® New Drug Application (NDA) with the US Food and Drug Administration (FDA). Subsequently the Agency advised the Company that it had formally accepted the resubmission and set 26 August 2013 as the Prescription Drug User Fee Act (PDUFA) date for action.

“We are delighted the FDA has formally accepted our resubmission,” said QRxPharma Managing Director and Chief Executive Officer, Dr John Holaday. “Assuming approval, we anticipate product launch with our US commercialisation partner, Actavis, before the end of this calendar year” added Holaday.

57. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in a no agreement letter, that the Complete Response Letter stated that QRX had not satisfied the combination rule, and that QRX was challenging the FDA’s determinations that MoxDuo must satisfy the combination rule and that QRX failed to satisfy the requirements of the combination rule. The statement in the foregoing paragraph was also misleading for failure to disclose that QRX had lost both appeals of the Complete Response Letter.

58. On September 25, 2013, QRX issued its annual report for 2013. It stated, in pertinent part, that: “The FDA has previously confirmed that the Company’s Combination Rule Trial (Study 008) satisfied efficacy requirements, and that there were no safety issues in any of the studies submitted as part of the original NDA.”

59. The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA had rejected the protocols for Study 008 in a no agreement letter, that the Complete Response Letter stated that QRX had not satisfied the combination rule because it failed to show superiority, and that QRX was challenging the FDA’s determinations that MoxDuo must satisfy the combination rule and that QRX failed to satisfy the requirements of the combination rule. The statement in the foregoing paragraph was also misleading for failure to disclose that QRX
had lost both appeals of the June 2012 Complete Response Letter. The statements were also misleading because the FDA Memo stated that study results indicated that MoxDuo’s safety profile was no better than morphine and oxycodone.

60. On November 26, 2013, QRX issued a press release entitled *QRxPharma Refiles MoxDuo New Drug Application with the FDA*. The press release stated, in pertinent part:

_Sydney, Australia and Bedminster, New Jersey_ – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today that the Company resubmitted its MOXDUO® New Drug Application (NDA). At a meeting in early October, the United States Food and Drug Administration (FDA) provided QRxPharma with guidance on its requirements for the NDA refiling as well as data validation documentation.

“We are confident that our refiled NDA will confirm the validity of the data defining the product’s respiratory safety advantages and we are hopeful that the FDA will view them favourably in their consideration of the benefits of immediate release MOXDUO as a therapeutic option for the millions of patients who suffer from acute pain,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “We were encouraged by our candid dialogue with the FDA throughout this process, and will continue to liaise closely with the Agency to bring MOXDUO to market.”

The FDA previously confirmed that the Company’s Combination Rule Trial, Study 008, satisfied efficacy requirements and that there were no efficacy or safety issues identified in any of the studies submitted in the original NDA.

QRxPharma completed an audit of the more than 30 million data points for oxygen desaturation from Study 022. We believe these data demonstrate a significant respiratory safety advantage for MOXDUO over equi-analgesic doses of morphine or oxycodone. Furthermore, MOXDUO provides a lower starting dose and finer dose titration steps than acute pain opioids presently available, giving greater flexibility to physicians and patients as the need for pain relief is balanced with lower risks of side effects.

We expect the FDA to schedule an Advisory Committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following this submission, projected for late May, 2014.

61. The foregoing statement was false and misleading for failure to disclose that The statement in the foregoing paragraph was misleading because it omitted to disclose that the FDA
had rejected the protocols for Study 008 in a no agreement letter, that the Complete Response Letter stated that QRX had not satisfied the combination rule because it failed to show superiority, and that QRX was challenging the FDA’s determinations that MoxDuo must satisfy the combination rule and that QRX failed to satisfy the requirements of the combination rule. The statement in the foregoing paragraph was also misleading for failure to disclose that QRX had lost both appeals of the June 2012 Complete Response Letter. The foregoing statement was also false and misleading because it failed to disclose that Study 022 had failed its primary endpoint, showing MoxDuo to be less safe than morphine or oxycodone with respect to oxygen desaturation, and that the alleged positive results provided by QRX were based on a post hoc analysis that is of little to no value to the FDA.

**Loss Causation**

62. On June 27, 2012, on news that the FDA had not approved MoxDuo, and had instead issued a “complete response letter” rejecting MoxDuo, QRX’s ADRs declined 47%, from $7.37 to $3.88 on higher than average trading volume. The heightened, but undisclosed risk, indeed near certainty, of the FDA rejecting MoxDuo due to the FDA’s earlier issuance of the no agreement letters were concealed from the market and materialized on June 27, 2012. This was a only a partial disclosure of the true state of affairs and a partial materialization of the concealed risks because QRX continued to conceal that: (i) the FDA had rejected the protocols for Study 008 in a no agreement letter; and (ii) the Complete Response Letter stated that QRX had not satisfied the combination rule.

63. On April 17, 2014, the Australian Stock Exchange and the OTC Market in the U.S. suspended trading in QRX’s securities at the request of QRX, due to pending news from the company.
64. During the trading halt, on April 22, 2014, the FDA Center for Drug Evaluation and Research released the FDA Memo which recommended denying QRX’s application for MoxDuo. The FDA Memo painted a very different picture of MoxDuo’s history than QRX had led investors to believe.

65. Specifically, and omitted from Holaday’s prior representations, the FDA Memo which recommended denying QRX’s new drug application for MoxDuo stated that: (i) the FDA has, throughout the approval process, told QRX that it required that MoxDuo offer a safety or efficacy advantage against comparable doses of morphine and oxycodone, (ii) the FDA sent the Company the no agreement letter prior to the initiation of Study 008, and the no agreement letter disclosed that the FDA did not agree with QRX’s “proposed primary efficacy endpoint and statistical approach” for Study 008; (iii) QRX appealed the FDA’s June 2012 Complete Response Letter rejecting the NDA on two separate occasions in 2012, and lost both appeals; and (iv) Study 022 failed its primary endpoint, and did not show a safety advantage for MoxDuo.

66. The FDA Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) conducted its meeting to evaluate MoxDuo on April 22, 2014, which was live-streamed and thus available to the public. The AADPAC’s final report, dated April 22, 2014, which reflected the contents of the meeting, noted a number of findings by the AADPAC which supported the determination that MoxDuo studies did not show the safety or efficacy benefits claimed by the Company. Specifically, the AADPAC voted unanimously to recommend against approval of MoxDuo. The final report noted in pertinent part:

**DISCUSSION:** Please discuss whether the overall opioid-related adverse event data provide evidence of clinically meaningful differences in safety between MoxDuo and morphine and/or MoxDuo and oxycodone.

**Committee Discussion:** Members of the committee restated concerns with the quality of data supporting a respiratory safety advantage when addressing the overall safety profile of MoxDuo. One member stated that, among the many
analyses conducted post-hoc, only the oxygen desaturation data suggested any safety advantage. Without confidence in the clinical significance of the oxygen desaturation data, the committee could not conclude a clinically meaningful difference in overall safety.

**VOTE:** Given the available safety data, has the Applicant provided evidence that MoxDuo is safer than morphine and oxycodone when these drugs are used individually and at comparable doses?

**Vote Result:** Yes – 0 / No – 14 / Abstain – 0

**Committee Discussion:** The committee unanimously agreed that given the available safety data, the Applicant has not provided evidence that MoxDuo is safer than morphine and oxycodone when these drugs are used individually and at comparable doses. The committee members again cited insufficient evidence to determine a safety benefit for MoxDuo. Members reiterated discomfort with the large number of post-hoc analyses, and the lack of a consistent signal of benefit among the resultant data. Please see the transcript for details of the committee discussion.

**VOTE:** Should MoxDuo be approved for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate?

a. **DISCUSSION:** If you voted “No” to question #4, please discuss whether there are any additional studies to support approval of this product in the future.

**Vote Result:** Yes – 0 / No – 14 / Abstain – 0

**Committee Discussion:** The committee unanimously agreed that MoxDuo should not be approved for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate. The position of the committee was summarized by the Chair, in reiterating the committee’s lack of confidence with any clinically meaningful safety difference, combined with the consensus from the sponsor and the agency that there is no notable efficacy difference. Given this lack of efficacy benefit and uncertain safety benefit, the Chair stated that there is “no basis for approval.”

67. On April 22\(^4\), 2014, the Company issued a press release entitled QRxPharma Issues Statement on MOXDUO® Advisory Committee Meeting announcing that the “AADPAC has voted to recommend against approval of MoxDuo”. The press release stated in pertinent part:

Sydney, Australia and Bedminster, New Jersey - QRxPharma (ASX: QRX and OTCQX: QRXPY) announced today that the United States Food and Drug

\(^4\) This press release was issued before 9:30 AM on April 23 Australian time, and therefore was released after market close on April 22 in the US.
Administration (FDA) Anesthetic and Analgesic Drug Products Advisory Committee has voted to recommend against approval of MoxDuo, an immediate release Dual Opioid® for the treatment of moderate to severe acute pain. The Advisory Committee found the Company did not provide sufficient evidence to warrant approval of MoxDuo at this time.

“We are obviously disappointed in the outcome of today’s meeting, but remain confident in the advantages of MoxDuo compared to morphine and oxycodone. This is a necessary therapy for patients with moderate to severe acute pain,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “We are committed to bringing to market safer therapies for pain, such as MoxDuo, and preventing opioid abuse.”


69. As a result of the adverse disclosures on April 22, 2014, concerning FDA’s rejection of the new drug application for MoxDuo, the price of QRX ADRs dropped over 83% on April 23, 2014 when trading resumed – from a prior opening price of $3.40 to $0.42 per share, on unprecedented volume.

70. On May 2, 2014, QRX issued a press release stating that Holaday had stepped down as Managing Director and Chief Executive Officer of the Company.

71. On May 19, 2014, QRX released a slide presentation for investors that contained the following slides:
Frequently Asked Questions

• Did FDA conclude that Moxduo did not meet the Combination Rule based on a failure of Study 008 to receive a Special Protocol Assessment agreement?
  – **Answer:** No. QRxPharma followed the Special Protocol Assessment (SPA) process for Study 008, which was designed to meet the requirements of FDA’s Combination Rule. QRxPharma received feedback from FDA that Study 008 was sufficient to satisfy the Combination Rule as FDA was interpreting it at that time. Comments were received from FDA regarding the study design, including a change in the primary endpoint.

Frequently Asked Questions

• Did FDA conclude that Moxduo did not meet the Combination Rule based on a failure of Study 008 to receive a Special Protocol Assessment agreement? (continued):
  – **Answer:** That feedback came in a “No Agreement” letter and contained additional comments. QRxPharma incorporated all FDA recommendations in the revised protocol, and re-submitted it for final approval. FDA declined to review the final revised protocol in a third cycle due to resource constraints. QRxPharma then initiated Study 008. Study 008 was successfully completed and met all endpoints specified by FDA, including the primary endpoint.
72. On July 9, 2014, the Company announced that its’ Chairman of the Board, Dr. Peter Farrell, and Directors Dr. Gary Pace, Peter Campbell, and Michael Quinn resigned from the QRX Board.

73. Subsequently, on August 14, 2014, the Company announced that it was halting further development work on the MoxDuo portfolio of products. Specifically, the Company issued a press release which stated in pertinent part:

The management team has since conducted a detailed review of the MoxDuo technology with particular emphasis on the EOR meeting with the FDA and made a recommendation to the Board to halt all further development of the MoxDuo IR, CR and IV programs. The Board of QRxPharma has agreed with, and accepted this recommendation.

The Company believes that the MoxDuo program will require a repeat Phase 2 clinical study, followed by one or more pivotal Phase 3 clinical studies. The FDA has advised that agreement on a Special Protocol Assessment (SPA) would be unlikely for these studies and given specific issues related to the design of these clinical studies, such as a primary endpoint of 90% SpO2 and flexible dosing, both which have been strongly encouraged by FDA, the likelihood of success is now in considerable doubt.

The Company estimates the time and cost for such a development program to be significant and is not commercially justified given the limited residual patent life.

**ADDITIONAL ALLEGATIONS SUPPORTING SCIENTER**

74. In addition to the foregoing allegations, Holaday’s scienter can be inferred from the fact that the fraud related to a core operation of the company. QRX had no products for sale during the class period, and MoxDuo was the company’s only product under development. Virtually all of QRX’s public communications, other than those regarding financing, were focused on discussions of MoxDuo, and QRX presented itself as entirely focused on obtaining FDA approval for MoxDuo, and QRX’s fundraising was for the purpose of funding FDA trials. For example, QRX appended to its press releases a description of itself which provided, in full:

QRxPharma Limited is an Australian based, commercial-stage specialty pharmaceutical company focused on the development and commercialisation of new pain management and
abuse prevention products. Based on a development strategy that focuses on enhancing the clinical utility of currently approved compounds as well as bringing new products to market, the Company's product portfolio includes both late and early stage clinical drug candidates with the potential for reduced risks and improved patient outcomes. The Company's refiled New Drug Application for its lead product candidate immediate release MOXDUO® for the treatment of acute pain, is presently under review at the US Food and Drug Administration. QRxPharma has entered into strategic agreements with Actavis Inc., Paladin Labs Inc., Aspen Group and Teva for the commercialisation of immediate release MOXDUO in the US, Canada, Australia (including New Zealand and Oceania), South Africa and Israel. The Company's clinical pipeline includes an intravenous (IV) and controlled release (CR) formulation of MOXDUO. QRxPharma is also collaborating with Aesica Formulation Development Limited, for the worldwide promotion of QRxPharma's proprietary Stealth Beadlets™ abuse deterrence technology. For more information, visit www.qrxpharma.com

75. Holaday’s scienter can also be inferred from Holaday’s frequent commentary on the MoxDuo approval process. On several occasions during the class period, Holaday personally described the process for approving MoxDuo, and its progress.

76. Holaday also had access to information that would have revealed the fraud. As CEO, Holaday had access to the, the complete response letters, QRX’s appeals, and the denials of those appeals. The Company conducted numerous meetings with the FDA, and it is the practice of the FDA to issue meeting minutes for each such meeting. Not only did Holaday have access to those minutes, QRX had the ability to contact the FDA regarding their contents and seek clarification, pursuant to FDA guidelines. Holaday also had the no agreement letters in his file and underlined pertinent portions.

77. Holaday’s scienter can also be inferred from his abrupt resignation, on May 13, 2014, very soon after the revelation of the fraud.

78. Holaday’s scienter can further be inferred from his blatant attempts to conceal the fraud and to make false exculpatory statements. On April 22, 2014, Defendant Holaday held an investor conference call to discuss the AADPAC’s unanimous vote recommending against approval of MoxDuo, and in an exchange with caller David Langsam (“Caller”) from Biotech
Daily, Defendant Holaday stated in part:

At 16:37:

Caller: Did you actually receive as the FDA says in its background materials a “no agreement letter” from them on 008, or did you not receive a “no agreement letter”?

Holaday: You know, I don’t recall a “no agreement letter”, there was an issue regarding statistical problems that were minor, but we asked them to review our protocol for 008 before we began the study. They agreed that it was properly designed and meets the combination rule as applied at that time. Subsequently, prior to our expected approval in 2012, they came back with a Complete Response Letter, wherein they said that we needed to show a benefit for this product.

Caller: So you’re saying that Dr. Bob Rappaport is incorrect.

Holaday: Yes. The actual rule states equal to or better than, even this guideline for combination for over the counter products, which was pointed out during today’s meeting by the Chairman of the Committee.

Caller: Now I wanna clear up the “no agreement letter”. Did QRX receive a letter from the division, from Bob Rappaport, or from any of his staff, saying that they did not agree to the 008 trial?

Holaday: No.

Caller: So the FDA has published incorrect information in their background letter.

Holaday: David. I do not know of a “no agreement letter”. I do know that they had informed us in writing that we had met the combination rule at that time and that they could not further review this product until such time as they, the statistical analysis of this product, until they have decided how best to manage the combination of two drugs in the same category.

Caller: I’ll just ask that in a different way, so the FDA have given you a letter which you’ve got saying that you have met for the 008 trial the combination rule?

Holaday: That’s correct, and they also agreed to that in our pre-NDA meetings as well as our end of phase 2 meetings.

The foregoing statement contains numerous misrepresentations of material fact including 1) QRX had received a no-agreement letter, a copy of which was in Holaday’s possession, 2) the FDA never agreed that Study 008 was properly designed, 3) the FDA had never
informed QRX that they met the combination rule.

80. The scienter of QRX can be established through Holaday’s scienter, which is attributable to QRX. But even if Holaday was found not to have scienter, QRX’s scienter can be inferred from the scienter of other officers of QRX. Given the importance of regulatory approval to QRX, it is virtually certain that an officer with sufficient seniority at QRX such that knowledge can be attributable had scienter with respect to the true facts of the FDA’s positions regarding QRX.

**CLASS ACTION ALLEGATIONS**

81. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of all persons or entities who purchased or otherwise acquired QRX ADR securities from December 6, 2010 to April 23, 2014 inclusive.

82. Excluded from the Class are Defendants, 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.

83. 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 Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe 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 QRX 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.

84. Plaintiffs’ claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendant Holaday’s wrongful conduct in
violation of federal law, which is complained of herein.

85. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

86. 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 federal securities laws were violated by Defendant Holaday’s acts as alleged herein;

(b) whether statements made by Defendant Holaday to the investing public during the Class Period omitted material facts about the business, operations, and prospects of QRX;

(c) whether the price of QRX shares were artificially inflated during the Class Period; and

(d) to what extent the members of the Class have sustained damages and the proper measure of damages.

87. 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 makes 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.

APPLICABILITY OF PRESUMPTIONS OF RELIANCE

Fraud on the Market Doctrine

88. QRX shares traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired the Company’s securities,
relying upon the integrity of the market price of QRX shares and the market information relating to QRX, and have been damaged thereby.

89. At all relevant times, the market for QRX securities was an efficient market for the following reasons, among others:

90. QRX ADRs met the requirements for listing, and were listed and actively traded on the OTC;

91. QRX’s common stock met the requirements for listing, and was listed and actively traded on the Australian Stock Exchange;

92. QRX was followed by numerous analysts that issued reports about it, including JP Morgan, Merriman Capital, RBS, Thompson Reuters, Global Data, Southern Cross Equities, Edison Investment Research, Streetwise Reports, and CIMB research.

93. As a regulated issuer in Australia and in the U.S., QRX filed periodic public reports with regulators; and

94. QRX regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.

95. QRX was followed by securities analysts employed by major brokerage firms, including JP Morgan, Merriman Capital, RBS, Thompson Reuters, Global Data, Southern Cross Equities, Edison Investment Research, Streetwise Reports, and CIMB research, which authored reports that were distributed to the sales force and certain customers of their respective brokerage firms.

96. As a result of the foregoing, the market for QRX securities promptly digested current information regarding QRX from all publicly available sources and reflected such
information in QRX’s ADR price. Under these circumstances, all purchasers of QRX securities during the Class Period suffered similar injury through their purchase of QRX securities at artificially inflated prices, and a presumption of reliance applies.

**Affiliated Ute**

97. Neither Lead Plaintiffs nor the Class need prove reliance - either individually or as a class because under the circumstances of this case, which involves a failure to disclose that Study 008 was not approved by the FDA, as described herein above, positive proof of reliance is not a prerequisite to recovery, pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security. As the Supreme Court explained, requiring plaintiffs to describe how they would have behaved had the omitted information been disclosed places an unrealistic burden on plaintiffs.
COUNT I

Violation of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against

Defendants QRX and Holaday

98. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

99. During the Class Period, Defendants QRX and Holaday carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (ii) cause Plaintiffs and other members of the Class to purchase QRX securities at artificially inflated prices.

100. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company’s securities in an effort to maintain artificially high market prices for QRX securities in violation of §10(b) of the Exchange Act and Rule 10b-5.

101. Defendants directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mail, engaged and participated in a continuous course of conduct to conceal adverse material information about QRX’s business, operations, and financial performance and prospects, as specified herein.

102. Defendants employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of QRX’s value, performance, and continued substantial growth. These acts included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in
order to make the statements made about QRX and its business, operations, and financial prospects in light of the circumstances under which they were made, not misleading. As set forth more particularly herein, Defendants further engaged in transactions, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company’s securities during the Class Period. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts, even though such facts were available to them. Defendants’ material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing QRX’s financial condition from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendant’s misstatements and/or omissions concerning the Company’s business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

103. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of QRX securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company’s securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired QRX securities during the Class Period at artificially high prices and were damaged thereby.
104. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were ignorant of their falsity and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding QRX and its business and prospects, which was not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their QRX securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices that they paid.

105. By virtue of the foregoing, Defendants violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

106. As a direct and proximate result of Defendants’ wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company’s securities during the Class Period.

107. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff’s purchases of securities giving rise to the cause of action.

**COUNT II**

**Violation of §20(a) of the Exchange Act Against the Defendant Holaday**

108. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

109. Defendant Holaday acted as a controlling person of QRX within the meaning of §20(a) of the Exchange Act as alleged herein. By virtue of his high-level position, ownership and contractual rights, participation in and/or awareness of the Company’s operations, and/or intimate knowledge of the false statements filed by the Company with the SEC and disseminated to the investing public, Defendant Holaday had the power to influence and control, and did influence and control, directly or indirectly, the decision making of
the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Defendant Holaday was provided with or had unlimited access to copies of the Company’s reports, press releases, public filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

110. In particular, Defendant Holaday had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

111. As set forth above, QRX and Holaday violated §10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of his position as a controlling person, Defendant Holaday is liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Defendant Holaday’s wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company’s securities during the Class Period.

112. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff’s purchases of securities giving rise to the cause of action.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure with Plaintiffs serving as class representatives;

B. Awarding compensatory damages in favor of Plaintiffs and the other Class
members against Defendants for all damages sustained as a result of Defendants’ wrongdoing,
in an amount to be proven at trial, including interest thereon; and

C. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: January 4, 2016

Respectfully submitted,

THE ROSEN LAW FIRM P.A.

By: /s/ Laurence Rosen
Laurence Rosen
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Lead Counsel for Plaintiffs and Class
CERTIFICATE OF SERVICE

I hereby certify that on this, the 4th day of January 2016, a true and correct copy of the foregoing document was served by CM/ECF to the parties registered to the Court’s CM/ECF system.

/s/ Laurence Rosen
Laurence Rosen