UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KARIM KHOJA, on behalf of himself and all others similarly situated,

Plaintiff,

v.

OREXIGEN THERAPEUTICS, INC., JOSEPH P. HAGAN, MICHAEL A. NARACHI, and PRESTON KLASSEN,

Defendants.

AND ALL CONSOLIDATED CASES

Case No.: 15-CV-540 JLS (JLB)

ORDER (1) GRANTING IN PART AND DENYING IN PART THE MOVING DEFENDANTS' REQUEST FOR JUDICIAL NOTICE, (2) DENYING LEAD PLAINTIFF'S REQUEST FOR JUDICIAL NOTICE, AND (3) GRANTING IN PART AND DENYING IN PART THE MOVING DEFENDANTS' MOTION TO DISMISS

(ECF Nos. 98, 98-15, 103-1)

Presently before the Court is Moving Defendants Joseph P. Hagan, Michael A. Narachi, and Preston Klassen's Motion to Dismiss Consolidated Complaint for Violation of the Federal Securities Laws ("Mot.," ECF No. 98).[1] Also before the Court are Lead Plaintiff Karim Khoja's Response in Opposition to ("Opp'n," ECF No. 103) and the Moving Defendants' Reply in Support of ("Reply," ECF No. 105) the Motion, as well as

[1] Defendant Orexigen Therapeutics, Inc., filed a voluntary petition for bankruptcy under Chapter 11, *see In re Orexigen Therapeutics, Inc.*, No. 18-10518-KG (Bankr. D. Del. filed Mar. 12, 2018); consequently, pursuant to the automatic bankruptcy stay, *see* 11 U.S.C. § 362(a), Orexigen is not a party to the Motion.

the Moving Defendants' Request for Judicial Notice ("Defs.' RJN," ECF No. 98-15) and Reply in Support of their RJN ("RJN Reply," ECF No. 106) and Lead Plaintiff's Declaration of Alayne Gobeille in Support of His Opposition ("Pl.'s RJN," ECF No. 103-1), which the Court construes as a request for judicial notice. The Court vacated the hearing and took the Motion under submission without oral argument pursuant to Civil Local Rule 7.1(d)(1). *See* ECF No. 107. Having carefully considered Lead Plaintiff's Consolidated Complaint ("CC," ECF No. 55) and the material appropriately incorporated by reference, the Parties' arguments, and the law, the Court **GRANTS IN PART AND DENIES IN PART** the Moving Defendants' RJN, **DENIES** Plaintiff's RJN, and **GRANTS IN PART AND DENIES IN PART** the Moving Defendants' Motion as follows.

BACKGROUND[2]

I. Factual Background

Defendant Orexigen is a developmental stage biotechnology firm focusing on the development of pharmaceutical product candidates for the treatment of obesity. CC ¶ 7. Orexigen is a small company with approximately fifty employees. *Id.* ¶ 33. Its common stock is traded on the NASDAQ. *Id.* ¶¶ 33, 131(a). Defendant Narachi is Orexigen's CEO and a director, *id.* ¶ 34, Defendant Hagan is Orexigen's Chief Business Officer and Acting CFO, *id.* ¶ 36, and Defendant Klassen is Orexigen's Head of Global Development. *Id.* ¶ 38.

Orexigen's primary obesity treatment candidate is Contrave, *id.* ¶ 7, which is designed to treat overweight and obese persons already at high risk for major adverse cardiovascular events ("MACE"), defined as myocardial infarction (heart attack), stroke,

[2] The facts alleged in Plaintiff's Consolidated Complaint are accepted as true for purposes of the Moving Defendants' Motion. *See Vasquez v. Los Angeles Cnty.*, 487 F.3d 1246, 1249 (9th Cir. 2007) (holding that, in ruling on a motion to dismiss, the Court must "accept all material allegations of fact as true"). The Court also considers those materials outside the Consolidated Complaint that are properly incorporated by reference. *See Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018), *cert. denied*, 139 S. Ct. 2615 (2019); *see also infra* pages 15–21.

or cardiovascular death. *Id.* ¶¶ 8, 87. Contrave is made from two off-patent generic drugs, bupropion and naltrexone. *Id.* ¶ 66. Orexigen has a collaboration agreement with Takeda Pharmaceutical Company Limited to develop and commercialize Contrave in the United States, Canada, and Mexico. *Id.* ¶ 7.

Orexigen submitted a new drug application for Contrave to the United States Food and Drug Administration ("FDA"). *Id.* ¶ 49. Concerned that Contrave may cause adverse cardiovascular events because of its effect on blood pressure and heart rate, *id.* ¶ 127, in January 2011, the FDA mandated a randomized, double-blind, placebo-controlled clinical trial designed to assess the cardiovascular risks associated with Contrave (the "Light Study") before the new drug application could be approved. *Id.* ¶¶ 8, 49. The Light Study's Executive Steering Committee ("ESC") was chaired by Dr. Steven Nissen, a Department Chair of Cardiovascular Medicine at the Cleveland Clinic. *Id.* at 1 n.1. Orexigen initiated the Light Study in June 2012, and completed screening in December 2012, resulting in approximately 8,900 patients randomized for treatment. *Id.* ¶ 51. The FDA agreed that if the Light Study's interim analysis revealed that Contrave did not increase the risk of a major cardiac event by 40 percent or more, Contrave could be approved. *Id.* ¶¶ 51, 96, 126.

In November 2013, the Light Study's Data Monitoring Committee ("DMC") shared with Orexigen the completed interim results. *Id.* ¶ 52. The results, based on ninety-four MACE, which was approximately 25 percent of the planned MACE for the Light Study, indicated that Contrave reduced cardiovascular events by 41 percent compared with a placebo. *Id.* ¶¶ 70, 87. Specifically, thirty-five Contrave patients experienced MACE, whereas fifty-nine placebo patients did. *Id.* ¶ 88.

The Light Study's ESC, DMC, and Orexigen entered into a data access plan ("DAP"), pursuant to which all agreed to limit the number of people within Orexigen who had access to the interim results to just those individuals who needed to facilitate submission of Orexigen's marketing application to the FDA. *Id.* ¶ 53 & n.10. The Light Study's statistical review team, however, subsequently discovered that Orexigen had

leaked the positive interim data to over 100 people. *Id.* ¶¶ 10, 53. Among those to whom the data was leaked was Narachi, who publicly pledged in a November 25, 2013 *Forbes* article, "We're going to honor the integrity of [the Light Study's] blind so we don't screw it up and get the final analysis." *Id.* ¶¶ 9, 52, 58. Others who saw the data included investment bankers and several representatives from Takeda. *Id.* ¶ 58.

The FDA later confirmed in a September 10, 2014 report that Orexigen improperly had disseminated unblinded interim data "far beyond the intended core group." *Id.* (emphasis omitted). The Light Study's DMC "found that it [was] particularly concerning that members of Orexigen's Board of Directors . . . , who have financial interest in the outcome of the trial, were also provided full access to the unblinded data." *Id.* (emphasis omitted). Consequently, the FDA required Orexigen to sign a new DAP. *Id.* ¶¶ 11, 60.

At a June 4, 2014 meeting, the FDA reminded Narachi and Klassen that the 25 percent interim results have "a high degree of uncertainty and were likely to change with the accumulation of additional data." *Id.* ¶ 59. The FDA was also concerned that Orexigen's corporate leaders knew the 25% interim results. *Id.* ¶ 10. The FDA also noted that the unblinding violated Orexigen's data access plan and that the extent of the confidentiality breach of interim results in the Light Study was unprecedented. *Id.*

On July 2, 2014, Orexigen filed patent application number 14/322,810 (the "'810 Application") with the United States Patent and Trademark Office ("USPTO"), listing Klassen as the "patent applicant" and "inventor." *Id.* ¶¶ 12, 61. The '810 Application covered a new indication—a cardiovascular benefit—for Contrave based on the 25 percent interim data. *Id.* ¶ 66. The '810 Application explicitly included the 25 percent interim Light Study data, *id.* ¶¶ 12, 62, and noted:

> Surprisingly, rather than increasing the occurrence of MACE in this high risk patient population, the results indicate that treatment with [Contrave] decreases the occurrence of MACE in overweight and obese subjects with cardiovascular risk factors. Briefly stated, fewer subjects in the [Contrave] treatment group experienced a MACE even compared to placebo.

Id. ¶ 62 (alterations in original) (emphasis omitted). Pursuant to 35 U.S.C. § 122, Orexigen requested that the USPTO keep the '810 Application confidential. *Id.* ¶¶ 12 & n.6, 61.

On September 10, 2014, the FDA approved Contrave for commercial use, *id.* ¶¶ 14, 55, 126, and in December 2014, the Committee for Medicinal Products for Human Use ("CHMP"), the centralized expert advisory committee of the European Medicines Agency, adopted a positive opinion for Contrave and recommended that the European Commission grant a centralized marketing authorization.[3] *Id.* ¶ 63. The European Commission also informed Orexigen that it would review a draft decision granting marketing authorization for Contrave during a meeting of the Standing Committee scheduled for March 2015. *Id.*

On January 5, 2015, in hopes that the USPTO's publication of the 25 percent interim Light Study data would influence European regulators, Narachi and Klassen rescinded Orexigen's prior nonpublication request to the USPTO. *Id.* ¶¶ 14, 64–65. On January 8, 2015, the USPTO indicated that the '810 Application was "in the publication queue." *Id.* ¶ 14 (emphasis omitted). On February 5, 2015, Hagan and Narachi were awarded a stock option grant of 202,650 and 635,150 shares, respectively, at an exercise price of $5.34, *id.* ¶ 84, and on February 11, 2015, the USPTO advised Orexigen that the '810 Application would be issued as a patent on March 3, 2015. *Id.* ¶ 67.

On February 25, 2015, Klassen informed investors on a conference call that "there wo[uld]n't be any release of the [Light Study] information unless pre-specified boundaries [we]re hit." *Id.* (emphasis omitted). Orexigen's February 27, 2015 Form 10-K noted that "[d]isclosure of interim results of ongoing clinical trials, including disclosure of interim results related to the protection of intellectual property . . . could significantly affect our product development costs or adversely impact our ability to maintain or receive additional regulatory approvals." *Id.* ¶ 68 (alteration in original) (emphasis omitted).

On March 3, 2015, the USPTO issued U.S. Patent No. 8,969,371 (the "'371 Patent") from the '810 Application. Defs.' RJN Ex. B, ECF No. 98-4; *see also* CC ¶¶ 15, 69. That

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[3] Contrave is marketed under the name Mysimba in Europe. *Id.* ¶ 63 n.16.

same day, Orexigen also filed a Form 8-K with the United States Securities and Exchange Commission ("SEC") announcing the publication of the '371 Patent and releasing the 25 percent interim Light Study Results. CC ¶¶ 15, 69, 87. The Form 8-K noted that the '371 Patent "incorporate[d] data from [the Light Study]," and that the '371 Patent "contain[s] claims related to a positive effect of Contrave on [cardiovascular ("CV")] outcomes" based on an "analysis . . . conducted based on 94 observed an adjudicated [MACE], which was approximately 25% of the planned MACE for the Light Study." *Id.* ¶ 87. The Form 8-K further explained that the interim analysis "was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval" and that "[a] larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes." *Id.* Orexigen did not consult the FDA, Dr. Nissen, or Takeda prior to filing the Form 8-K. *Id.* ¶ 15.

Soon thereafter, *Forbes* reported that FDA senior official Dr. John Jenkins had stated that the FDA was unaware that Orexigen's '810 Application contained the 25 percent interim data and expressed "serious concerns" about Orexigen's disclosure of the interim data. *Id.* ¶¶ 93, 118. The FDA reported that it was "very disappointed by Orexigen's actions" and warned patients and physicians that it was "critical that the[] interim data [] not be misinterpreted." *Id.* ¶ 93 (alterations in original). The FDA noted that "[e]ndpoints with less than 100 total events are statistically unreliable and were to be viewed with extreme caution. *Id.* ¶ 118.

Late on March 3, 2015, in response to the *Forbes* article, Orexigen published a press release, explaining that it "filed patent applications based on the results in order to preserve the potential for additional intellectual property." *Id.* ¶¶ 94, 119. It also explained that "[d]uring the course of the study, the FDA informed [Orexigen] it had determined that the Light Study would not serve as the postmarketing requirement for Contrave; a new trial would be required." *Id.* ¶ 94. Orexigen added that the new trial would start "later this year," and results "are anticipated by 2022." *Id.* Orexigen added that "[t]his morning the USPTO published the patent and supporting documentation, and [Orexigen] believed it

was appropriate and necessary to make sure this information was equally available to all investors." *Id.* ¶¶ 94 (emphasis omitted), 119.

Although Orexigen's stock had closed at $5.79 per share on March 2, 2015, it closed at $7.64 per share on March 3, 2015, trading as high as $9.37 per share. *Id.* ¶¶ 16, 89, 117. More than 95.7 million Orexigen shares were traded on March 3, 2015, a "highly unusual trading volume," *id.* ¶¶ 89, 117, especially when compared to the average daily trading volume of approximately 3 million shares per day. *Id.* ¶ 16 n.7.

Analysts responded positively to the March 3, 2015 Form 8-K. *Id.* ¶¶ 90–91. For example, Analyst Simos Simeonidis from RBC Capital Markets noted that "[w]e view the news as very significant" and "[t]he newly revealed data demonstrated that not only is Contrave safe to use from a CV standpoint, but it actually appears to have a CV benefit." *Id.* ¶ 90 (emphasis omitted). Consequently, he rated Orexigen's shares to "outperform." *Id.* Similarly, analysts at Piper Jaffray noted that the Light Study's interim results "[c]ould turn the obesity/metabolic syndrome market on its head. We see this [cardiovascular outcome trial ("CVOT")] effect as surprisingly positive and it has several implications, in our view for the potential of Contrave." *Id.* ¶¶ 17, 90 (emphasis omitted). Leerink analyst Paul Matteis reported that "[t]he data this morning show a statistically significant Contrave benefit." *Id.* ¶ 91 (emphasis omitted). Wells Fargo analyst Matthew J. Andrews, in analyzing the data, noted that "the 'holy grail' for treating cardiometabolic diseases is demonstration of a CV mortality benefit, which to date has not been demonstrated by an obesity therapeutic." *Id.* ¶¶ 17, 91 (emphasis omitted).

On March 4, 2014, the *Wall Street Journal* published an article explaining that the FDA "considers the preliminary data 'far too unreliable to conclude anything further about cardiovascular safety.'" *Id.* ¶ 96 (emphasis omitted). The article noted that "LIGHT study data was disclosed inappropriately" previously and that the FDA consequently had decided that "Orexigen would have to launch a new study to satisfy the conditions of the approval of its Contrave drug." *Id.* (emphasis omitted). The *Wall Street Journal* reported that Dr. Nissen, "the lead researcher for the study[,] is upset." *Id.* Dr. Nissen noted that "he

was not aware of the interim study results until yesterday," "the disclosure was not approved by the data monitoring committee or the trial's executive committee," and Orexigen's business management was not included in the list of individuals with approved access to the data. *Id.* (emphasis omitted). On March 4, 2015, the price of Orexigen's stock closed at $8.49 per share, *id.* ¶¶ 16, 97, 120, "again on unusually high trading volume of more than 40.5 million shares." *Id.* ¶¶ 97, 120.

A March 5, 2015 *Forbes* article reported that "[t]here is widespread speculation that Orexigen used the excuse of the patent filing to publicly reveal the interim results of the trial." *Id.* ¶ 70 (emphasis omitted). The *Forbes* article further reported that critics believed that "[d]isclosing the results, through the medium of a patent filing and an SEC disclosure, is a deeply cynical and manipulative action." *Id.* (emphasis omitted). *Forbes* also speculated that Orexigen's repeated disclosure of the Light Study interim results could potentially threaten its relationship with the FDA and its ability to obtain further drug approvals. *Id.* ¶ 121. On March 5, 2015, Orexigen's stock closed at $8.01 per share, down from its opening price of $8.50 per share. *Id.* ¶¶ 19, 121.

After the close of trading on March 5, 2015, *Forbes* published another report, which included criticisms of Orexigen and its decision to release the interim trial data by Dr. Jenkins, the FDA's director of the Office of New Drugs. *Id.* ¶¶ 18, 122. Dr. Jenkins criticized the released data as "unreliable," "misleading," and "likely false," and warned that Orexigen "could face fines, civil penalties, or even the withdrawal of Contrave from the market" if it did not complete the new post-marketing study that the FDA would require. *Id.* On March 6, 2015, the price of Defendant Orexigen's stock dropped to $6.76 per share in intraday trading and closed at $7.10 per share, "again on unusually high trading volume." *Id.* ¶¶ 19, 123, 125.

On March 13, 2015, Orexigen filed a Form S-8 Registration Statement, registering six million shares of common stock at a proposed maximum offering price of $7.08 per share. *Id.* ¶¶ 20, 85; *see also* Defs.' RJN Ex. I, ECF No. 98-11, at 3.

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In its March 26, 2015 Form 8-K, Orexigen announced that Contrave had received marketing authorization in Europe. CC ¶¶ 21, 72, 99. Over nine million shares of Orexigen's stock traded on that day, with stock prices increasing from an opening price of $6.89 on March 26, 2015, to a closing price of $7.54 on March 27, 2015. *Id.* ¶ 72.

Also on March 26, 2015, Light Study researchers discovered that Contrave's purported 25 percent interim heart benefit vanished once the additional 50 percent Light Study results were considered. *Id.* ¶¶ 21, 74. The Light Study's ESC unanimously voted to terminate the Light Study and to release immediately the 50 percent interim data. *Id.* ¶¶ 21, 74, 127. Defendants were shown the 50 percent interim data demonstrating that the 25 percent interim cardiovascular benefit had disappeared. *Id.* ¶¶ 21, 74, 99, 127. Dr. Nissen began to draft a press release disclosing the 50 percent Light Study data and termination of the Light Study, which Takeda approved but Orexigen refused to authorize. *Id.* ¶¶ 21, 75.

On May 8, 2015, Orexigen filed a Form 8-K containing a press release announcing its business and financial results for the first quarter ended March 31, 2015. *Id.* ¶ 100. The press release noted that Contrave's "clinical trial program also includes a double-blind, placebo-controlled cardiovascular outcomes trial known as the Light Study." *Id.* (emphasis omitted). Orexigen also filed a Form 10-Q, *id.* ¶ 103, noting that its share price might be impacted by "announcements regarding [its] clinical trials, including [ ] the Light Study and the post-marketing required clinical trials, including the new CVOT, for Contrave." *Id.* ¶ 104 (second alteration in original). The Form 10-Q also represented that "additional analysis of the interim results or new data from the continuing Light Study, including safety-related data, and the additional cardiovascular outcomes trial, may produce negative or inconclusive results, or may be inconsistent with the conclusion that the interim analysis was successful." *Id.* (emphasis omitted). The Form 10-Q also noted that "[a]ny failure by [Orexigen] or delay in completing [its] clinical trials, including the Light Study, or in obtaining regulatory approvals, could cause a delay in the commencement of product revenues and cause [its] research and development expenses to increase." *Id.* ¶ 105.

That same day, Orexigen also hosted an earnings conference call for analysts and investors. *Id.* ¶¶ 22, 107. In response to a question about whether the Light Study had been terminated, Klassen represented that the "Light Study is continuing and we are continuing to engage both Orexigen and Takeda with the FDA and with ESC and DMC regarding ultimately the status of the study, but it's an ongoing entity as of right now." *Id.* ¶ 108 (emphasis omitted). In response to a query about the 50 percent interim data, Klassen responded:

> We have passed the 50% time point and as we've stated before, those results are viewed by the Data Monitoring Committee and it wasn't a planned look by the sponsors, like the 25% was. The 25% was special because it was for regulatory purposes and so we have had 50% time point.

Id. ¶ 109 (alteration in original). Narachi added:

> The results from the 50% analysis . . . only come out in the context of wrapping up the trial or as a final analysis. So, if the decision is made to terminate the trial early and focus resources on the next CVOT, which is what we have been advocating, then I think results would come out sooner.

Id. ¶ 110 (emphasis omitted). Narachi also noted that, "if there was a decision to terminate the [Light Study] . . . , that would be a disclosure that we would make." *Id.* ¶ 111 (emphasis omitted).

On May 12, 2015, Orexigen and Takeda announced the discontinuation of the Light Study, *id.* ¶¶ 24, 126, but did not reveal the 50 percent data. *Id.* ¶¶ 24. They noted that they were "pleased that the Light Study is now being terminated and want[ed] to thank the patients and all those involved in the study." *Id.* ¶ 27 (alteration in original) (emphasis omitted).

Minutes later, Dr. Nissen and the Cleveland Clinic issued a press release announcing both the termination of the Light Study and the 50 percent interim data. *Id.* ¶¶ 24, 75, 126, 127. The 50 percent Light Study data revealed that at 192 MACE, the difference between

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the Contrave and placebo groups shrank to 12 percent and was no longer statistically significant. *Id.* ¶ 127. Dr. Nissen noted:

> These results do not confirm the cardiovascular benefits of Contrave claimed by Orexigen in the patent application based on the data obtained at the 25 percent time point in the trial . . . . These results show neither benefit nor harm for patients taking the drug, but are consistent with the requirement by the FDA that the Light Trial demonstrate an absence of a doubling of cardiovascular risk for patients taking the drug . . . . The inconsistency of effects on cardiovascular outcomes between the first 25 percent and the second 25 percent of the Light Study clearly illustrates the risks inherent in pre-judgment of clinical trial results based upon an interim analysis and demonstrate why interim results should remain confidential during any ongoing trial.

Id. ¶ 126 (emphasis omitted).

In an article appearing on *Forbes.com*, Dr. Nissen claimed that "[p]atients were misled, investors were misled." *Id.* ¶ 127 (emphasis omitted); *see also id.* ¶ 25. Dr. Nissen also noted that Orexigen had refused to approve a press release publicizing the 50 percent Light Study data for six weeks. *Id.* ¶¶ 25, 127. An article published in *Medscape* on that same day quoted Dr. Nissen as saying:

> Essentially, when they [Orexigen] filed the patent the company chose what they were going to put in there and what they were going to leave out . . . . We felt it was in the public interest to take an unprecedented step and release the 50% data because we couldn't allow unreliable data to be used in clinical decision making. We had a duty to the public and also to the investment community, to tell the truth.

Id. ¶ 128 (alteration in original); *see also id.* ¶ 26. The price of Orexigen's common stock fell from an opening price of $6.75 on May 11, 2015, to $5.02 per share at the close of May 13, 2015. *Id.* ¶¶ 26, 130.

II. Procedural Background

On March 10, 2015, Plaintiff Lisa Colley filed a class action complaint against Defendants, alleging (1) violation of § 10(b) of the Securities Exchange Act of 1934 (the

"1934 Act") and Rule 10b-5, and (2) violation of § 20(a) of the 1934 Act. *See generally* ECF No. 1. The case was originally assigned to United States District Court Judge M. James Lorenz. *See id.* Two related actions—*Stefanko v. Orexigen Therapeutics, Inc.*, No. 15-CV-00549 JAH (JLB) (S.D. Cal.), and *Yantz v. Orexigen Therapeutics, Inc.*, No. 15-CV-557 CAB (MDD) (S.D. Cal.)—were filed on March 11, 2015. *See* ECF No. 4.

On May 12 and 13, 2015, a number of competing motions for consolidation, appointment of lead plaintiff, and approval of lead counsel were filed. *See generally* ECF Nos. 26, 27, 28, 29, 32, 33, 34, 35, 37, 38. On June 15, 2015, Lead Plaintiff informed Judge Lorenz that his motions were unopposed. *See* ECF No. 42. Consequently, Judge Lorenz granted Lead Plaintiff's motions on June 22, 2015. *See generally* ECF No. 43.

On June 26, 2015, Judge Lorenz recused himself from this action, which was reassigned to this Court. ECF No. 46. On August 20, 2015, Lead Plaintiff filed his Consolidated Complaint, *see generally* ECF No. 55, which Defendants moved to dismiss on October 5, 2015. *See generally* ECF No. 62.

On May 19, 2016, the Court granted in part and denied in part Defendants' motion. *See generally* ECF No. 76. In ruling on the motion, the Court granted in part and denied in part Defendants' request for judicial notice, which requested that the Court take judicial notice of or incorporate by reference twenty-two documents. *See id.* at 14–19. On the merits of Lead Plaintiff's first cause of action, the Court limited its analysis to the adequacy of Lead Plaintiff's allegations concerning whether Defendants had made material misrepresentations or omissions of fact. *See id.* at 21–31. The Court dismissed with prejudice Plaintiff's first cause of action to the extent it was predicated on material misstatements or omissions appearing in Orexigen's March 3, 2015 Form 8-K and press release, *see id.* at 22–26, and dismissed without prejudice Plaintiff's first cause of action to the extent it was predicated on material misstatements or omissions appearing in Orexigen's May 8, 2015 Forms 8-K and 10-Q and earnings conference call. *See id.* at 26–31. Consequently, the Court also dismissed Lead Plaintiff's second and third causes of

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action. *See id.* at 31–36. The Court granted Lead Plaintiff thirty days to file an amended complaint. *Id.* at 36.

On June 16, 2016, Lead Plaintiff requested that "the Court enter judgment so that Lead Plaintiff c[ould] appeal the Order to the United States Court of Appeals for the Ninth Circuit." *See* ECF No. 77. On June 27, 2016, having received no objection from Defendants, the Court directed the Clerk of the Court to enter judgment. *See* ECF Nos. 78, 79.

On July 26, 2016, Lead Plaintiff filed a notice of appeal. *See* ECF No. 80. Following the close of briefing, *see* ECF No. 82, Orexigen filed for bankruptcy. *See In re Orexigen*, No. 18-10518-KG (Bankr. D. Del. filed Mar. 12, 2018).

On August 13, 2018, the Ninth Circuit issued a decision affirming in part and reversing in part the Court's May 19, 2016 Order. *See generally Khoja*, 899 F.3d 988. The Ninth Circuit first clarified the standards for judicial notice and incorporation by reference, affirming some and reversing other of the Court's decisions to judicially notice or incorporate by reference Defendants' proffered documents. *See id.* at 998–1008. The Ninth Circuit next affirmed in part and reversed in part the Court's dismissal of Lead Plaintiff's first cause of action based on the elements of falsity and materiality. *See id.* at 1008–17. Specifically, the Ninth Circuit determined that the Court erred in dismissing Lead Plaintiff's first cause of action with respect to the March 3, 2015 Form 8-K to the extent it was premised on the publication of the 25 percent interim results because Lead Plaintiff "pled a plausible claim that Orexigen had a duty to disclose that the 25 percent interim results in the March 2015 Form-8K were unreliable." *See id.* at 1009–10. The Ninth Circuit also determined that the Court erred to the extent it dismissed Plaintiff's first cause of action with respect to the March 2015 press release's statement about the publication of the '371 Patent because "Orexigen arguably gave the false impression that it played no role in revealing the 25 percent interim results." *Id.* at 1013. As for the May 8, 2015 Forms8-K and 10-Q and earnings conference call, the Ninth Circuit concluded that Lead Plaintiff plausibly alleged that "Orexigen gave the false impression that the Light

Study was still underway," *id.* at 1014, 1016, and that Orexigen was obligated to disclose the 50 percent interim results. *Id.* at 1015, 1017. Finally, the Ninth Circuit affirmed the Court's dismissal of Lead Plaintiff's second cause of action, *see id.* at 1017–18, and reversed the Court's dismissal of Lead Plaintiff's third cause of action. *See id.* at 1018.

Lead Plaintiff declined the opportunity to amend his Consolidated Complaint on remand. *See* ECF No. 96 at 3:9–10, 6:5–6, 7:17–20. Consequently, following a status hearing, *see* ECF No. 92, the Court set a briefing schedule, *see* ECF No. 97, pursuant to which the Moving Defendants filed the instant Motion. *See generally* ECF No. 98.

REQUESTS FOR JUDICIAL NOTICE

I. Legal Standard

"Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *Khoja*, 899 F.3d at 998 (citing *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). "There are two exceptions to this rule: the incorporation-by-reference doctrine, and judicial notice under Federal Rule of Evidence 201." *Id.*

Pursuant to Federal Rule of Evidence 201(b), "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." "Accordingly, '[a] court may take judicial notice of matters of public record without converting a motion to dismiss into a motion for summary judgment.'" *Khoja*, 899 F.3d at 999 (quoting *Lee*, 250 F.3d at 689). "But a court cannot take judicial notice of disputed facts contained in such public records." *Id.* (citing *Lee*, 250 F.3d at 689).

"Even if a document is not attached to a complaint, it may be incorporated by reference into a complaint if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003) (citing *Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002); *Branch v. Tunnell*, 14 F.3d 449, 453–54 (9th Cir. 1994), *overruled on other*

grounds by Galbraith v. Cnty. of Santa Clara, 307 F.3d 1119 (9th Cir. 2002); *Venture Assoc. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431(7th Cir. 1993)). "'[T]he mere mention of the existence of a document is insufficient to incorporate the contents of a document' under *Ritchie*." *Khoja*, 899 F.3d at 1002 (quoting *Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1038 (9th Cir. 2010)). Nonetheless, a document may still form the basis of the plaintiff's claim where "the claim necessarily depended on the[document]." *Id.* (citing *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005)). "However, if the document merely creates a defense to the well-pled allegations in the complaint, then that document did not necessarily form the basis of the complaint." *Id.*

When a document is incorporated by reference, "the district court may treat such a document as part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *Ritchie*, 342 F.3d at 908; *see also Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006) ("The court may treat . . . a document [incorporated by reference] as 'part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6).'") (citing *Ritchie*, 342 F.3d at 908). Nonetheless, "it is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint." *Khoja*, 899 F.3d at 1003.

II. The Moving Defendants' Request for Judicial Notice

The Moving Defendants ask the Court to incorporate by reference nine documents:

(1) Center for Drug Evaluation & Research, U.S. Food & Drug Admin., Summary Review for Regulatory Action for Application No. 200063Orig1s000 (Sept. 10, 2014), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/200063Orig1s000SumR.pdf (Defs.' RJN Ex. A, ECF No. 98-3), which the Moving Defendants offer "for background facts about the Light Study and the FDA's regulatory process with respect to Contrave, including that the Light Study launched in June 2012 with more than 8,900 patients; the Light Study was initially designed to potentially satisfy the FDA's post-marketing requirement; the FDA agreed that if the study met certain conditions, Orexigen's previously denied New Drug Application . . . could be

resubmitted; Orexigen resubmitted the NDA in December 2013; and the FDA approved Contrave in September 2014," *see* Defs.' RJN at 4–5;

(2) U.S. Patent No. 8,969,371 (filed July 2, 2014) (Defs.' RJN Ex. B, ECF No. 98-4), which the Moving Defendants offer "for background facts about Orexigen's U.S. patent Application and the issuance of the Company's patent," including "the dates [Orexigen] filed a provisional and full patent application; that the U.S. Application included the 25% Interim Analysis data; and when the [USPTO] . . . published the '371 patent," *see* Defs.' RJN at 5;

(3) Orexigen Therapeutics, Inc., Current Report (Form 8-K) (Mar. 3, 2015), *available at* http://www.sec.gov/edgar/searchedgar/companysearch.html (Defs.' RJN Ex. C, ECF No. 98-5), which the Moving Defendants offer "so the Court has a complete picture of the information provided to investors on March 3, 2015—including robust cautionary language about the 25% Interim Analysis data that is omitted by Plaintiff from the Complaint" and "understands the context in which the alleged misrepresentations were made and . . . additional disclosures made by Defendants at the same time," *see* Defs.' RJN at 5;

(4) Simos Simeonidis, RBC Capital Markets, *Orexigen Therapeutics Inc: LIGHT Interim Data Reveal Contrave Positive CV Effect; Extend IP by 7 Years*, Equity Research: First Glance (Mar. 3, 2015) (Defs.' RJN Ex. D, ECF No. 98-6), which the Moving Defendants offer "for what was said therein and when," specifically, that "the obvious caveat . . . is that [the 25 percent Interim Analysis data] was an early, interim look, based on 25% of the events," *see* Defs.' RJN at 5–6 (quoting Defs.' RJN Ex. D at 46);

(5) Paul Matteis & Jason M. Gerberry, Leerink Partners LLC, *Orexigen Therapeutics, Inc.: 25% Interim LIGHT Analysis Shows Stat. Sig Contrave Benefit on CV Outcomes* (Mar. 3, 2015) (Defs.' RJN Ex. E, ECF No. 98-7), which the Moving Defendants offer "for what was said therein and when," specifically, that "the data should be interpreted with cautious optimism due to the small number of events," *see* Defs.' RJN at 6 (quoting Defs.' RJN Ex. E at 51);

(6) Matt Herper, *The FDA Is Forcing Orexigen to Do a Second Safety Study Because of Contrave Disclosures*, www.forbes.com (Mar. 3, 2015, 3:33 PM), *available at* http://www.forbes.com/sites/matthewherper/2015/03/03/the-fda-will-force-orexigen-to-do-a-second-safety-study-because-of-contrave-disclosures/ (Defs.' RJN Ex. F, ECF No. 98-8), which the Moving Defendants offer "to show the timing and content of an FDA spokesperson's statements

as reported on Forbes.com, including that the March 3 Forbes Article was published hours after the March 3 8-K and the FDA spokesperson characterized the 25% Interim Analysis data as 'preliminary,' 'far too unreliable to conclude anything,' and 'should not be interpreted to suggest that Contrave reduces the risk for [CV] events,'" *see* Defs.' RJN at 6 (quoting Defs.' RJN Ex. F at 57);

(7) Matt Herper, *Top FDA Official Says Orexigen Study Result 'Unreliable,' 'Misleading,'* www.forbes.com (Mar. 5, 2015, 5:28 PM), *available at* http://www.forbes.com/sites/matthewherper/2015/03/05/top-fda-official-says-orexigen-data-unreliable-likely-false/ (Defs.' RJN Ex. G, ECF No. 98-9), which the Moving Defendants offer "so the Court has the alleged corrective disclosure document before it in deciding Defendants' Motion," *see* Defs.' RJN at 6;

(8) Press Release, Orexigen Therapeutics, Inc., Takeda Pharmaceuticals and Orexigen Therapeutics Announce Termination of the Cardiovascular Outcomes Study (Light Study) of the Obesity Drug Contrave (naltrexone HCl and bupropion HCl) (May 12, 2015), *available at* http://ir.orexigen.com/phoenix.zhtml?c=207034&p=irol-newsArticle&ID=2046959 (Defs.' RJN Ex. H, ECF No. 98-10), which the Moving Defendants offer "for facts about the timing and content of Orexigen and Takeda's announcement of the Light Study's termination—including that the companies issued the press release four days after Defendants' statements to investors on May 8, 2015, and announced that they had accepted the Light Study Executive Steering Committee's . . . recommendation to terminate the Light Study," *see* Defs.' RJN at 6; and

(9) Orexigen Therapeutics, Inc., Registration Statement (Form S-8) (Mar. 16, 2015) (Defs.' RJN Ex. I, ECF No. 98-11), which the Moving Defendants offer "for the fact that it states the 'Proposed Maximum Offering Price Per Share' of $7.08 is just an 'estimate' made pursuant to Rule 457(h) of the Securities Act of 1933 'solely for purposes of calculating the registration fee,'" *see* RJN at 7 (quoting Defs.' RJN Ex. I at 68).

The Moving Defendants also ask the Court to take judicial notice of the following document:

(10) Exhibit 3 to Plaintiff-Appellant's Motion for Judicial Notice, *Khoja v. Orexigen Therapeutics, Inc.*, No. 16-56069 (9th Cir. filed Dec. 2, 2016), ECF No. 14-4, which is a March 8, 2016 article titled "Effect of Naltrexone-Buproprion on Major Adverse Cardiovascular Events in Overweight and

> Obese Patients With Cardiovascular Risk Factors: A Randomized Clinical Trial," co-authored by Steven E. Nissen, M.D., and published in the *Journal of the American Medical Association* (Defs.' RJN Ex. K, ECF No. 98-13), and which the Moving Defendants offer "only [for] the existence of the article, and the fact that Dr. Nissen and his co-authors made three public statements about the termination of the Light Study: (i) that '[t]he [ESC] recommended trial termination on May 12, 2015, and [Orexigen and Takeda] agreed[';] (ii) that '[t]he academic leadership of the [Light Study] recommended termination of the trial and the sponsor agreed[';] and (iii) that "[t]he study's academic leadership recommended termination of the trial,'" *see* Defs.' RJN at 7–8 (quoting Defs.' RJN Ex. K at 87, 88, 91).

The Court previously incorporated by reference Exhibits A through I. *See* ECF No. 76 at 18. Lead Plaintiff did not contest on appeal the propriety of the Court's decision as to Exhibits B, C, and H, and the Ninth Circuit affirmed the Court's ruling as to Exhibits A, D, E, F, G, and I. *See* Defs.' RJN at 3; *see also Khoja*, 899 F.3d at 1002–08. The Moving Defendants therefore contend that the Court may incorporate by reference Exhibits A through I in deciding the instant Motion. *See* Defs.' RJN at 3. The Moving Defendants additionally urge the Court to take judicial notice of Exhibit K, which "is a publicly available medical-journal article that *Plaintiff* asked the Ninth Circuit to take judicial notice of on appeal." *Id.* (emphasis in original). In a footnote, Lead Plaintiff objects to Exhibits C, D, and E as "improperly offered to characterize the 25% interim data"; Exhibits F and G as "improperly offered to characterize disclosures to the market"; and Exhibit K as "improperly offered to prove truth of matters asserted." Opp'n at 1 n.2.

Plaintiff does not object to the incorporation by reference of Exhibits A or B, and the Court finds that it is appropriate to incorporate those documents by reference for the limited purposes enumerated in the Moving Defendants' RJN.

As for Exhibit C, the Consolidated Complaint refers extensively to the March 3, 2015 Form 8-K, *see, e.g.*, CC ¶¶ 87–88, which also forms the basis of Lead Plaintiff's claims predicated upon false and misleading omissions in that very filing. *See, e.g.*, *id.* ¶¶ 87–92. Although "what inferences [the C]ourt may draw from [the] incorporated

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document should . . . be approached with caution," *see Khoja*, 899 F.3d at 1003, Exhibit C is appropriately incorporated by reference.

Regarding Exhibits D and E, the Ninth Circuit concluded that "the reports form the basis of Khoja's claim that the market relied on Orexigen's claims about the 25 percent interim results after 'numerous security analysts' followed and wrote reports about Orexigen." *Id.* at 1004. The Ninth Circuit therefore held that this Court "did not abuse its discretion by incorporating these reports." *Id.* The Court therefore concludes that it may incorporate by reference these documents.

Regarding Exhibit F, the Ninth Circuit noted that Lead Plaintiff "claims that Orexigen's response to the article was truly part of its scheme to inflate its stock values" and consequently concluded that "because the article triggered the alleged scheme, the article formed the basis of the scheme." *Id.* at 1004. The court therefore held that this Court "did not abuse its discretion by incorporating the article." *Id.* The Court therefore again concludes that it may incorporate by reference Exhibit F.

As for Exhibit G, the Ninth Circuit reasoned that, according to the Consolidated Complaint, "the article revealed the materiality of Orexigen's misrepresentations and omissions about the 25 percent interim results." *Id.* at 1005. "Because such materiality forms the basis of Count I, the district court did not abuse its discretion by incorporating this article." *Id.* The Court therefore concludes that it is appropriate to incorporate by reference Exhibit G.

Lead Plaintiff does not object to the Moving Defendants' request that the Court incorporate by reference Exhibits H or I. Regarding Exhibit H, it is clear that the May 12, 2015 press release forms the basis of Lead Plaintiff's claims, *see* CC ¶ 126; consequently, the Court may incorporate Exhibit H into the Consolidated Complaint. As for Exhibit I, the Ninth Circuit concluded that "the district court did not abuse its discretion by incorporating this document into the Complaint" because certain of Lead Plaintiff's allegations concerning the March 13, 2015 Form S-8 "form the basis of [his] claims."

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Khoja, 899 F.3d at 1006. Accordingly, the Court concludes that it may properly incorporate by reference Exhibit I.

Finally, regarding Exhibit K, the Court may take judicial notice that Plaintiff sought judicial notice of the underlying article before the Ninth Circuit. Nonetheless, it would be inappropriate to take judicial notice of the facts contained within the filing. The Court therefore **DENIES** the Moving Defendants' request that the Court take judicial notice of Exhibit K to show that the ESC recommended termination of the Light Study on May 12, 2015.

Accordingly, the Court **GRANTS IN PART AND DENIES IN PART** the Moving Defendants' RJN (ECF No. 98-15), as outlined above. Specifically, the Court incorporates by reference Exhibits A through I but declines to take judicial notice of Exhibit K.

III. Lead Plaintiff's Request for Judicial Notice

Although Lead Plaintiff did not formally request judicial notice or incorporation by reference of any documents, he does offer two exhibits attached to the Gobeille Declaration:

(1) Exhibit A to Debtor's Motion for Entry of Interim and Final Orders (I) Authorizing Debtor to (A) Continue Prepetition Insurance Program; (B) Pay Any Pre[-]petition Premiums and Related Obligations; and (C) Renew or Enter into New Insurance Arrangements; and (II) Granting Related Relief, *In re Orexigen Therapeutics, Inc.*, No. 18-10518-KG (Bankr. D. Del. filed Mar. 12, 2018), ECF No. 11-1 (Pl.'s RJN Ex. 1, ECF No. 103-2), which is a list of Orexigen's insurance policies that Lead Plaintiff offers to show that "the [Moving] Defendants are covered by a wasting $40 million Directors and Officers insurance policy," *see* Opp'n at 1 n.1; and

(2) Michael O'Riordan, *LIGHT Stopped: Contrave CVD Safety Study Halted Following Premature Release of Data*, www.medscape.com (May 12, 2015), *available at* https://www.medscape.com/viewarticle/844575_print (Pl.'s RJN Ex. 2, ECF No. 103-3), which Lead Plaintiff offers to show that the JAMA article does not create any ambiguity as to the data that the Light Study was stopped, *see* Opp'n at 20 n.14.

The Court declines to take judicial notice of Exhibit 1. Although the Court may take judicial notice of the fact that Defendants filed a Schedule of Insurance Policies in

Orexigen's bankruptcy proceeding, the Court cannot take judicial notice of the facts contained in the filing, including the existence or amount of a Directors and Officers Insurance Policy covering the Moving Defendants. *See Khoja*, 899 F.3d at 999. In any event, the existence of such a policy is not relevant to the issues raised by the Motion.

The Court also declines to take judicial notice of Exhibit 2. Again, the Court may take judicial notice that the article was published, but it cannot take judicial notice of the facts alleged therein, especially not to resolve a factual dispute at the pleading stage. *See Khoja*, 899 F.3d at 1000 (concluding that it is improper to take judicial notice of a document when "there is a reasonable dispute as to what [it] establishes") (quoting *Reina-Rodriguez v. United States*, 655 F.3d 1182, 1193 (9th Cir. 2011)). Accordingly, the Court **DENIES** Lead Plaintiff's Request for Judicial Notice.

THE MOVING DEFENDANTS' MOTION TO DISMISS

I. Legal Standard

Rule 12(b)(6) permits a party to raise by motion the defense that the complaint "fail[s] to state a claim upon which relief can be granted," generally referred to as a motion to dismiss. The Court evaluates whether a complaint states a cognizable legal theory and sufficient facts in light of Federal Rule of Civil Procedure 8(a), which requires a "short and plain statement of the claim showing that the pleader is entitled to relief." Although Rule 8 "does not require 'detailed factual allegations,' . . . it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). In other words, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." *Twombly*, 550 U.S. at 555 (alteration in original). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (alteration in original) (quoting *Twombly*, 550 U.S. at 557).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting

Twombly, 550 U.S. at 570); *see also* Fed. R. Civ. P. 12(b)(6). A claim is facially plausible when the facts pled "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). That is not to say that the claim must be probable, but there must be "more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). "[F]acts that are 'merely consistent with' a defendant's liability" fall short of a plausible entitlement to relief. *Id.* (quoting *Twombly*, 550 U.S. at 557). Further, the Court need not accept as true "legal conclusions" contained in the complaint. *Id.* at 678–79 (citing *Twombly*, 550 U.S. at 555). This review requires "context-specific" analysis involving the Court's "judicial experience and common sense." *Id.* at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (quoting Fed. R. Civ. P. 8(a)(2)).

Further, "[c]laims brought under Rule 10b-5 . . . must meet Federal Rule of Civil Procedure 9(b)'s particularity requirement that '[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.'" *In re Dura Pharm., Inc. Sec. Litig.*, 452 F. Supp. 2d 1005, 1016 (S.D. Cal. 2006) (alteration in original) (quoting Fed. R. Civ. P. 9(b)) (citing *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1014 (9th Cir. 2005), *cert. denied* 546 U.S. 1172 (2006); *Yourish v. Cal. Amplifier*, 191 F.3d 983, 993 (9th Cir. 1999)). "In addition, in 1995, Congress enacted the Private Securities Litigation Record Act of 1995 (PSLRA) and altered the pleading requirements in private securities fraud litigation by requiring a complaint plead with particularity both falsity and scienter." *Id.* at 1016–17 (quoting *Daou Sys.*, 411 F.3d at 1014) (internal quotation marks omitted).

The Court will grant leave to amend unless it determines that no modified contention "consistent with the challenged pleading . . . [will] cure the deficiency." *DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992) (quoting *Schriber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986)).

II. Analysis

Lead Plaintiff alleges two surviving causes of action: (1) Count I for violations of § 10(b) of the 1934 Act and Rule 10b-5(b) against all Defendants, and (2) Count III for violations of § 20(a) of the Exchange Act against the Moving Defendants. *See* CC ¶¶ 142–55. The Court addresses each in turn below.

A. Section 10(b) and Rule 10b-5

"Section 10(b) of the . . . 1934 [Act] forbids (1) the 'use or employ[ment] . . . of any . . . deceptive device,' (2) 'in connection with the purchase or sale of any security,' and (3) 'in contravention of' [SEC] 'rules and regulations.'" *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341 (2005) (quoting 15 U.S.C. § 78j(b)). "Rule 10b-5 forbids, among other things, the making of any 'untrue statement of a material fact' or the omission of any material fact 'necessary in order to make the statements made . . . not misleading.'" *Id.* (quoting 17 C.F.R. § 240.10b-5). "The basic elements of a Rule 10b-5 claim, therefore, are: (1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." *Daou Sys.*, 411 F.3d at 1014 (citing *Dura Pharms.*, 544 U.S. at 341–42).

The Moving Defendants move to dismiss with prejudice Lead Plaintiff's Section 10(b) and Rule 10b-5 claims for failure adequately to plead (1) scienter as to all misrepresentations, and (2) loss causation as to the March 3, 2015 misrepresentations. *See* Mot. at 1–3, 20.

1. Scienter

A private securities plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The "required state of mind" is "scienter," *i.e.*, "a mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976); *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 975 (9th Cir. 1999), *abrogated on other grounds by S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776 (9th Cir. 2008); *In re Peerless Sys. Corp. Sec. Litig.*, 182 F. Supp. 2d 982, 987–88 (S.D. Cal. 2002).

"[T]he PSLRA requires plaintiffs to plead, at a minimum, particular facts giving rise to a strong inference of deliberate or conscious recklessness." *Silicon Graphics*, 183 F.3d at 979; *In re Wet Seal, Inc. Sec. Litig.*, 518 F. Supp. 2d 1148, 1157 (C.D. Cal. 2007). Recklessness amounts to "'an extreme departure from the standards of ordinary care, and . . . presents a danger of misleading buyers and sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" *DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 389 (9th Cir. 2002) (quoting *Hollinger v. Titan Cap. Corp.*, 914 F.2d 1564, 1569 (9th Cir. 1990)). To satisfy this pleading requirement, "the complaint must contain allegations of specific 'contemporaneous statements or conditions' that demonstrate the intentional or the deliberately reckless false or misleading nature of the statements when made." *Ronconi v. Larkin*, 253 F.3d 423, 432 (9th Cir. 2001); *In re Levi Strauss & Co. Sec. Litig.*, 527 F. Supp. 2d 965, 988 (N.D. Cal. 2007). The Court must consider competing inferences that could be drawn in favor of plaintiffs or defendants and determine whether plaintiffs have pled a "strong inference" of scienter which is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

a. The Ninth Circuit's Decision in *Khoja*

As an initial matter, Lead Plaintiff contends that the Ninth Circuit in "*Khoja* reasoned that almost all of the statements identified in the Complaint adequately pled material misstatements or omissions, and *with the requisite scienter*." Opp'n at 14 (emphasis added). The Moving Defendants rejoin that Lead "Plaintiff misreads the Ninth Circuit's decision and argues that court already decided scienter. It did not." Reply at 1.

The Moving Defendants are correct. The Ninth Circuit made explicit that it had made no determination as to the sufficiency of Lead Plaintiff's allegations of Defendants' scienter: "The district court's dismissal of Count I was based on the elements of falsity and materiality. Accordingly, the analysis here is limited to those issues." *Khoja*, 899 F.3d at 1008 (citing *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008)).

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b. The March 3, 2015 Statements

Lead Plaintiff alleges that Orexigen's March 3, 2015 Form 8-K and press release were materially false and misleading because they failed to disclose that "the 25% study results . . . were 'unreliable[]'" and that "Orexigen had made a request with the USPTO in January 2015 to have the patent publicly disseminated." CC ¶¶ 92, 94; *see also Khoja*, 899 F.3d at 1009–1010, 1012. The Moving Defendants contend that Lead Plaintiff has failed to allege that any of them had the requisite fraudulent intent. *See* Mot. at 12–16. Specifically, the Moving Defendants urge that any inference of scienter concerning the undisclosed unreliability of the 25 percent interim results is undercut by the cautionary language appearing in the March 3, 2015 Form 8-K concerning the preliminary nature of the data. *See id.* at 14. As for the omission of Defendants' role concerning the USPTO's publication of the '371 Patent from the press release, the Moving Defendants argue that the Consolidated Complaint contains no allegations that the Moving Defendants believed that the statements were misleading or intended to mislead investors by omitting additional detail about Orexigen's role in the process. *See id.* at 15–16. Finally, the Moving Defendants contend that Lead Plaintiff's additional allegations concerning their compensation, stock options, and the Form S-8 Registration Statement do not give rise to a strong inference of scienter. *See id.* at 16–18.

Lead Plaintiff counters that "[f]alsity and scienter often go hand-in-hand," Opp'n at 13 (citing *Daou*, 411 F.3d at 1015), and that the Ninth Circuit's finding of material falsity should be dispositive. *See id.* at 17–18. Further, as to the disclosure of the unreliable 25 percent interim results, Lead Plaintiff claims that he has alleged that the FDA told Narachi and Klassen that the 25 percent interim results had "a high degree of uncertainty," *id.* at 16, and that Hagan—as a signatory to the March 3, 2015 8-K and as the Chief Business Officer, Treasurer, and CFO of Orexigen—"was aware, or deliberately disregarded, the significance of releasing the 25% interim data." *Id.* at 16 n.7 (citing CC ¶¶ 36–37; *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 989 (9th Cir. 2008); *Medina v. Clovis Oncology, Inc.*, 215 F. Supp. 3d 1094, 1127 (D. Colo. 2017)). As for the publication of the

'371 Patent, Lead Plaintiff claims that "because each of the Defendants was aware of the materiality of the omitted information, it was reckless of them to fail to disclose it in their March 3, 2015 press release." *Id.* at 18. Moreover, "[b]ecause [revealing the interim results publicly] 'impact[ed] the financial health of Orexigen,' Defendants were obviously motivated to conceal responsibility for their failed gamble that Contrave provided a heart benefit," *id.* at 19 (quoting *Khoja*, 899 F.3d at 1012–13), and "Defendants were aware that they filed the patent confidentially and that they did so to maintain the appearance that they were maintaining the secrecy of the study data." *Id.* (citing CC ¶¶ 61–70).

The Court concludes that Lead Plaintiff adequately has alleged facts giving rise to a strong inference of scienter as to Klassen and Narachi's alleged material omissions on March 3, 2015, but not as to Hagan's. Regarding the March 3, 2015 disclosure of the unreliable 25 percent interim data in the Form 8-K, Lead Plaintiff alleges that, "[d]uring a June 4, 2014 meeting about Defendants' breach, the FDA reminded Defendants Narachi and Klassen that 25% interim results have 'a high degree of uncertainty and were likely to change with the accumulation of additional data.'" CC ¶ 59; *see also id.* ¶ 10. The Ninth Circuit held that, "once Orexigen chose to tout the apparently positive 25 percent interim results, Orexigen had the obligation also to disclose that they were likely unreliable," which the Consolidated Complaint sufficiently alleges that Orexigen failed to do. *See Khoja*, 899 F.3d at 1010. Lead Plaintiff therefore alleges that, despite knowing that the 25 percent interim results were unreliable, Klassen and Narachi failed to disclose as much in the March 3, 2015 8-K. At the pleading stage, these allegations give rise to an inference of scienter "at least as compelling as any opposing inference of nonfraudulent intent." *See Tellabs*, 551 U.S. at 314.

Although the presence of cautionary language in the Form 8-K does give rise to an inference of nonfraudulent intent, *see, e.g.*, Mot. at 14; Defs.' RJN Ex. C, the inference that Klassen and Narachi acted with deliberate or conscious recklessness is at least as compelling. Defendants could have announced the publication of the '371 Patent without touting the 25 percent interim results, *see* CC ¶ 70 n.18, or they could have disclosed that

the 25 percent interim results were considered unreliable. *See Khoja*, 899 F.3d at 1010. Instead, Defendants published the data with certain qualifiers but, as the Ninth Circuit recognized, "telling investors that the data might change is different from saying the data already has 'a high degree of uncertainty' and is likely to change." *Id.* Consequently, the inference that Klassen and Narachi misleadingly disclosed the unreliable 25 percent interim data artificially to inflate the price for Orexigen's stock is equally compelling. *See, e.g.*, CC ¶¶ 69–71, 145.

As the Moving Defendants note, however, "[t]here is no allegation that Hagan attended the June 4, 2014 meeting, or that any information from that meeting was ever transmitted to him." Mot. at 13 n.10. And "[w]ithout allegations that each of the [Moving] Defendants that signed various [of Orexigen's] public filings knew those public filings contained misstatements, the [Moving] Defendants' signatures on those public filings alone does not give rise to a strong inference of scienter." *See In re Hansen Nat. Corp. Sec. Litig.*, 527 F. Supp. 2d 1142, 1160 (C.D. Cal.), *judgment entered*, 2007 WL 3274427 (Oct. 16, 2007); *see also* Mot. at 13 n.10 (citing *In re LDK Solar Sec. Litig.*, No. C0705182WHA, 2008 WL 4369987, at *8 (N.D. Cal. Sept. 24, 2008)).

Lead Plaintiff therefore urges that the Light Study and its 25 percent interim results were of such importance to Orexigen that Hagan must have known of the unreliability of the preliminary data, allowing the Court to conclude that Lead Plaintiff has alleged a strong inference of scienter as to Hagan. *See* Opp'n at 14–15, 17–18. In so arguing, Lead Plaintiff relies heavily on the Ninth Circuit's decisions in *South Ferry*, 542 F.3d 776, and *Berson*, 527 F.3d 982. The Moving Defendants counter that this "core operations" inference "fails to impute knowledge to Hagan, who is not alleged to have knowledge of the unnamed FDA employee's opinion." Reply at 7–8.

The Court must agree with the Moving Defendants. Lead Plaintiff alleges that Hagan "served at all relevant times as the Company's Chief Business Officer, Treasurer and Acting CFO," CC ¶ 36, and that his "individual goals emphasized developing Contrave for markets both at home and abroad." *Id.* ¶ 82. But, unlike Klassen and Narachi, *see, e.g.*,

id. ¶¶ 10, 34, 36, 52, 59, there are no allegations that Hagan ever met with the FDA or was in any way involved in the Light Study. Rather, Lead Plaintiff alleges that Hagan "was to '[e]ffectively lead and manage the finance and accounting teams as Orexigen transitions into a commercial stage company' and '[l]ead the ROW [rest of the world] partnering process and make significant progress toward establishing partnership(s) to further develop and commercialize Contrave outside North America.'" *Id.* ¶ 82. Consequently, although Lead Plaintiff's allegations do reveal that Hagan's responsibilities at Orexigen were connected to Contrave generally, they appear to have been related more to its financial and marketing aspects. The Court therefore cannot infer that the FDA's interpretation of the 25 percent results must have been known to Hagan.

Neither *South Ferry* nor *Berson* compels a different conclusion. In *South Ferry*, for example, the Ninth Circuit concluded that allegations concerning management's role in the company "may independently satisfy the PSLRA where they are particular and suggest that defendants had actual access to the disputed information" or "may conceivably satisfy the PSLRA standard in a more bare form, without accompanying particularized allegations, in rare circumstances where the nature of the relevant fact is of such prominence that it would be 'absurd' to suggest that management was without knowledge of the matter." 542 F.3d at 786. The first circumstance is not applicable to Hagan, given the absence of any allegations that he was present at the June 4, 2014 meeting with the FDA or later discussed it with Klassen and Narachi. As for the second circumstance, the Ninth Circuit gave *Berson* as an example of the "exceedingly rare category of cases in which the core operations inference, without more, is sufficient under the PSLRA." *S. Ferry*, 542 F.3d at 785 n.3.

In *Berson*, which the Ninth Circuit discussed extensively in determining whether Orexigen had a duty to disclose the unreliability of the 25 percent interim data, *see Khoja*, 899 F.3d at 1010, the defendant company received "stop work" orders from two civilian agencies that accounted for approximately 80 percent of the company's revenue, meaning that the defendant company immediately ceased to earn money from those two agencies and "signal[ling] a heightened risk that the company never *w[ould]* earn the money." *See*

Berson, 527 F.3d at 984 (emphasis in original). Nonetheless, the defendant company "continued to count the stopped work as part of its 'backlog'—a term the company define[d] as the dollar value of the work it ha[d] contracted to do but ha[d]n't yet performed." *Id.* In concluding that the plaintiffs alleged a strong inference of scienter on behalf of the defendant company's CEO and CFO, the Ninth Circuit reasoned that "it is hard to believe that they would not have known about stop-work orders that allegedly halted tens of millions of dollars of the company's work." *Id.* at 988.

Unlike the stop work orders in *Berson*, the FDA's comments to Klassen and Narachi concerning the unreliability of the 25 percent interim data were not of such importance that "it would be 'absurd' to suggest that [Hagan] was without knowledge of the matter," particularly given the absence of any allegations that he was involved in the regulatory side of Orexigen in general or of Contrave in particular. *See S. Ferry*, 542 F.3d at 786 (quoting *Applied Signal*, 527 F.3d at 988). The Court therefore concludes that Lead Plaintiff has failed to allege facts giving rise to a strong inference that Hagan signed the March 3, 2015 8-K with deliberate recklessness to the unreliability of the 25 percent interim results reported therein.

A similar analysis applies to the allegedly material omission from the March 3, 2015 press release concerning Orexigen's role in the publishing of the '371 Patent. Lead Plaintiff alleges at length that it was "Narachi and Klassen [who] embarked on a deliberately reckless scheme to circumvent the FDA and to make the data public through the filing of a U.S. patent" and who later "rescinded the Company's nonpublication request to have the USPTO accomplish for Defendants indirectly what they knew they were prohibited from again doing directly – namely, revealing seemingly positive, but statistically suspect, 25% interim Light Study data." CC ¶¶ 12, 14 (emphasis omitted); *see also id.* ¶¶ 61–73. Consequently, although Lead Plaintiff adequately alleges a strong inference that Narachi and Klassen knew that the statement in the March 3, 2015 press release that "the USPTO published the patent and supporting documentation" was misleading, *see id.* ¶ 94, the same cannot be said of Hagan for the same reasons that the

Court cannot infer that Hagan must have known that the FDA considered the interim 25 percent data unreliable.

Accordingly, the Court **GRANTS IN PART AND DENIES IN PART** the Moving Defendants' Motion as to the Moving Defendants' scienter as to the May 3, 2015 material omissions. Specifically, the Court **GRANTS** the Motion as to Hagan and **DENIES** the Motion as to Klassen and Narachi.

c. Orexigen's May 8, 2015 Statements

Lead Plaintiff also alleges that Defendants' May 8, 2015 Forms 8-K and 10-Q and earnings conference call were materially misleading because they misrepresented that the Light Study was ongoing by failing to disclose that the ESC had terminated the Light Study on March 26, 2015, and failed to disclose the 50 percent interim results. *See* CC ¶¶ 74–75, 100–12; *see also Khoja*, 899 F.3d at 1013–17. The Moving Defendants argue that Lead Plaintiff fails to plead scienter as to either of these statements because "the Complaint is internally contradictory with respect to the alleged timing of [the] Light Study termination," Mot. at 18, which "should be dispositive that Defendants were not deliberately reckless in failing to disclose that the Light Study had allegedly been terminated before May 8." *Id.* at 19 (citing *Tellabs*, 551 U.S. at 326; *id.* at 33 (Alito, J., concurring)). Further, "the Complaint lacks any allegations suggesting that Defendants—who said nothing about the 25% data *after* March 3, 2015 . . . —believed the failure to disclose the 50% data risked misleading investors." *Id.* (citing CC ¶¶ 99–112). Finally, "[t]he Complaint does not even attempt to connect the 2014 compensation goals (¶¶ 76–79), the 'well-timed' February stock grant (¶ 84), or the S-8 (¶ 85) to the May statements[, a]nd there are still no allegations that Defendants sold any stock." *Id.*

Lead Plaintiff counters that "[i]t is now law of the case that the Complaint's allegations 'support a plausible inference that the ESC terminated the Light Study before May 2015[,]'" and, "[e]ven if the ESC had only recommended terminating the study, . . . Defendants nevertheless had a duty to disclose that development." Opp'n at 20 (quoting *Khoja*, 899 F.3d at 1014; citing *id.* at 1016). "Further, given how intimately each of the

individual defendants was involved with the study, it is highly unlikely that any of them were unaware of the information." *Id.* at 20 n.12 (citing *S. Ferry LP*, 542 F.3d at 786; CC ¶¶ 10–11, 33–44, 52, 61). As for the 50 percent interim data, "[t]he fact that Defendants knew what the 50% data revealed well ahead of their May 2015 statements establishes an inference that they were made with scienter." *Id.* at 21–22 (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 50 (2011)). Lead Plaintiff also urges that "[t]he absence of stock sales does not undermine the existence of scienter" and that "where, as here, employee compensation is tied to facts of the alleged fraud, such 'particularized allegations' can establish scienter." *Id.* at 22 n.15 (citing *Matrixx*, 563 U.S. at 48; *No. 84 Emp'r-Teamster Joint Council Pension Tr. Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 944 (9th Cir. 2003)).

The Court concludes that Lead Plaintiff adequately has alleged scienter as to the Moving Defendants for the alleged material omissions from May 8, 2015. In light of the Ninth Circuit's conclusion that Lead Plaintiff's "allegations support a plausible inference that the ESC terminated the Light Study before May 2015," *see Khoja*, 899 F.3d at 1014, the Court rejects the Moving Defendants' argument that "the Complaint is internally contradictory with respect to the alleged timing of Light Study termination," *see* Mot. at 18, and in particular the Moving Defendants' reliance on Exhibit K to their Request for Judicial Notice, *see id.* at 18–19, of which the Court cannot properly take judicial notice. *See supra* page 20. The Court therefore accepts as its starting point that Lead Plaintiff plausibly alleges that the Light Study had already been terminated on March 26, 2015, and that Dr. Nissen informed the Moving Defendants of this development. *See, e.g.*, CC ¶ 21.

As to Klassen and Narachi, these allegations, coupled with Klassen's false statement that the "Light Study is continuing and . . . it's an ongoing entity as of right now," CC ¶ 108 (emphasis omitted), and Narachi's false assurance that Orexigen would disclose any decision to terminate the Light Study, *id.* ¶ 111, give rise to a strong inference of scienter on behalf of Klassen and Narachi as to their material omissions concerning the termination of the Light Study on May 8, 2015.

The question is closer concerning Hagan; nonetheless, the Court ultimately concludes that Lead Plaintiff's allegations as to Hagan give rise to a strong inference of scienter given Lead Plaintiff's allegations that Hagan knew of the March 26, 2015 termination of the Light Study, *see, e.g.*, *id.* ¶ 21, yet signed the May 8, 2015 Forms 8-K and 10-Q that misleadingly omitted this material information. *See, e.g.*, *id.* ¶ 37. The May 8, 2015 Form 8-K, for example, "suggest[ed] that the Light Study was ongoing," *id.* ¶ 101, by indicating that Orexigen's "clinical trial program also includes a double-blind, placebo-controlled cardiovascular outcomes trial known as the Light Study." *Id.* ¶ 100 (emphasis omitted). Similarly, the May 8, 2015 Form 10-Q also described the Light Study as "continuing," despite its prior termination. *See id.* ¶ 104. Coupled with Lead Plaintiff's allegations that Hagan knew that the Light Study had already been terminated,[4] the Court concludes that these allegations give rise to a strong inference of scienter on behalf of Hagan as to his material omissions concerning the termination of the Light Study.[5]

The same is true of Lead Plaintiff's alleged material omissions from May 8, 2015, concerning the 50 percent interim data. The Court again begins with Lead Plaintiff's allegation that, on March 26, 2015, the Moving Defendants "were actually shown the more mature 50% data demonstrating that the cardiovascular benefit the Company had earlier touted on March 3, 2015 was false." *Id.* ¶ 74. The Ninth Circuit concluded that, "by touting and publishing the 'surprisingly' positive 25 percent interim results, Orexigen created its own obligation to report that those results did not pan out after all." *Khoja*, 899 F.3d at 1017. Nonetheless, Lead Plaintiff alleges, when Klassen and Narachi participated in the earnings call on May 8, 2015, they failed to disclose the 50 percent interim results, even

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[4] Further, unlike the details concerning the publication of the '371 Patent and the FDA's comments concerning the unreliability of the 25 percent interim results, "it is hard to believe that [Hagan] would not have known" about the termination of an FDA-mandated study concerning Orexigen's "primary product candidate." *See Berson*, 527 F.3d at 988; *see also* CC ¶ 7.

[5] Because Narachi also signed the May 8, 2015 Form 10-Q, *see* CC ¶ 35, this reasoning would apply equally to him as to that individual filing.

when directly asked whether those results had been disclosed. *See* CC ¶¶ 109–10. Again, the Court concludes that these allegations give rise to a strong inference of scienter on behalf of Klassen and Narachi as to their material omissions concerning the 50 percent interim results.

Given the Ninth Circuit's conclusion that "Orexigen created its own obligation to report" the 50 percent interim results, *see Khoja*, 899 F.3d at 1017, the Court also concludes that Lead Plaintiff adequately has alleged scienter as to Hagan. Lead Plaintiff alleges that May 8, 2015 "Form 8-K failed to disclose that . . . the 50% interim data demonstrated that the Company's prior representations about Contrave's purported cardiovascular benefit were false." CC ¶ 101. Further, the May 8, 2015 Form 10-Q "misleadingly represented that 'additional analysis of the interim results or new data from the continuing Light Study, including . . . the additional cardiovascular outcomes trial, may produce negative or inconclusive results, or may be inconsistent with the conclusion that the interim analysis was successful,' without disclosing that the Company knew that more mature 50% interim data had already demonstrated that Contrave did not produce any heart benefit as the Company had earlier represented." *Id.* ¶ 104 (emphasis omitted). Again, coupled with Lead Plaintiff's allegations that Hagan knew the 50 percent interim data and that it contradicted the previously touted 25 percent interim data, the Court concludes that these allegations give rise to a strong inference of scienter on behalf of Hagan as to his material omissions concerning those results.[6]

The Court therefore **DENIES** the Moving Defendants' Motion as to Lead Plaintiff's allegations of the Moving Defendants' scienter concerning the alleged material omissions from May 8, 2015.

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[6] Again, because Defendant Narachi also signed the May 8, 2015 Form 10-Q, *see* CC ¶ 35, this reasoning would apply equally to him as to that individual filing.

2. Loss Causation

To demonstrate loss causation, a plaintiff must allege "a causal connection between the material misrepresentation and the loss." *Dura Pharm.*, 544 U.S. at 342; *see also* 15 U.S.C. § 78u-4(b)(4). In other words, "the complaint must allege that the practices that the plaintiff contends are fraudulent were revealed to the market and caused the resulting losses." *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1063 (9th Cir. 2008). A corrective disclosure must reveal some aspect of the alleged fraud to the market. *See Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 175 (2d Cir. 2005). Additionally, a plaintiff's allegations must reveal that "the defendant's 'share price fell significantly after the truth became known.'" *Metzler*, 540 F.3d at 1062 (quoting *Dura Pharm.*, 544 U.S. at 347). The Ninth Circuit recently has clarified that the plaintiff must only allege "facts that, if taken as true, plausibly establish loss causation," *In re Gilead*, 536 F.3d at 1057, "suggesting that loss causation is a fact-intensive inquiry better suited for determination at trial than at the pleading stage." *Rudolph v. UTStarcom*, No. C 07-04578 SI, 2008 WL 4002855, at *4 (N.D. Cal. Aug. 21, 2008) (citing *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 427 n.4 (3rd Cir. 2007); *Emergent Capital Inv. Mgmt., LLC v. Stonepath Grp., Inc.*, 343 F.3d 189, 197 (2d Cir. 2003)). Rule 9(b)'s heightened pleading standard applies to allegations of loss causation. *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 605 (9th Cir. 2014).

The Moving Defendants contend that Lead Plaintiff's claims predicated upon material misrepresentations or omissions made on March 3, 2015, must be dismissed for failure adequately to plead loss causation. *See* Mot. at 19. The Parties agree that two alleged corrective disclosures are relevant to Lead Plaintiff's March 3, 2015 claims, *compare id.* at 19–20, *with* Opp'n at 22–24: (1) the March 5, 2015 Forbes.com article, *see* CC ¶¶ 122–25; *see also* Defs.' RJN Ex. G; and (2) Dr. Nissen's May 12, 2015 press release. *See* CC ¶¶ 126–30.

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a. The March 5, 2015 Forbes.com Article

Lead Plaintiff alleges that an article published on March 5, 2015, by Forbes.com, in which a top FDA official, Dr. John Jenkins, "criticized Orexigen and its decision to release interim trial data," disclosed Defendants' March 3, 2015 misrepresentations. CC ¶ 122. Specifically, in the March 5, 2015 article, Dr. Jenkins "criticized the released data as 'unreliable,' 'misleading,' and 'likely false.'" *Id.* He "also warned that if 'Orexigen cannot find a way to set things right, it could face fines, civil penalties, or even the withdrawal of Contrave from the market.'" *Id.*

The Moving Defendants argue that this article "could not, by definition, be a corrective disclosure as the 'corrective' information was already known to the market." Mot. at 20 (citing *Katyle v. Penn Nat'l Gaming Inc.*, 637 F.3d 462, 473 (4th Cir. 2011)). In particular, the Moving Defendants rely on two articles published before Lead Plaintiff's alleged corrective disclosure: (1) a March 3, 2015 article published on Forbes.com, in which "an 'FDA spokesman' . . . characterized the 25% data as 'preliminary' and 'far too unreliable to conclude anything further about the [CV] safety of Contrave' and warned [the data] 'should not be interpreted to suggest that Contrave reduces the risk for [CV] events,'" *id.* (quoting CC ¶¶ 93, 118; Defs.' RJN Ex. F at 57); and (2) a March 4, 2015 story published by the *Wall Street Journal*, *id.* (citing CC ¶ 96), reporting that "[t]he [FDA] considers the preliminary data 'far too unreliable to conclude anything further about cardiovascular safety' and is concerned that premature disclosure of positive results can undermine the LIGHT study." CC ¶ 96.

Lead Plaintiff counters that the March 5, 2015 article contained "new, harmful information," specifically, that Dr. Jenkins "for the first time[] criticized the potential impact of the interim trial data as 'unreliable,' 'misleading' and 'likely false'" and "added that 'if Orexigen cannot find a way to set things right, it could face fines, civil penalties, or even the withdrawal of Contrave from the market," statements that "challenged the legitimacy and continuation of the Company's entire Contrave drug development program

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and caused the price of Orexigen stock to plummet as much as 16% in intraday trading." Opp'n at 23 (quoting CC ¶ 122) (citing *id.* ¶¶ 19, 123, 125).

The Court agrees with the Moving Defendants that the March 3, 2015 Forbes.com and March 4, 2015 *Wall Street Journal* articles already had disclosed that the FDA believed that the 25 percent interim data was "unreliable" before the March 5, 2015 Forbes.com article was published. Those articles, however, had not disclosed that Orexigen "could face fines, civil penalties, or even the withdrawal of Contrave from the market." *See* CC ¶ 122. The Court therefore concludes that the March 5, 2015 Forbes.com article revealed some aspect of the alleged fraud to the market and, consequently, that Lead Plaintiff adequately alleges loss causation as to the March 5, 2015 corrective disclosure.

b. Dr. Nissen's May 12, 2015 Press Release

Lead Plaintiff also alleges that Dr. Nissen's May 12, 2015 press release corrected Defendants' March 3, 2015 misrepresentations. *See* CC ¶¶ 126–28. Dr. Nissen's press release indicated that the "Light Trial . . . has been halted," *id.* ¶ 126, and that Orexigen's March 3, 2015 disclosure of the 25 percent interim analysis was "without the authorization of the study's academic leadership." *Id.* (emphasis omitted). Dr. Nissen reiterated that "the 25 percent interim data are not conclusive in establishing either benefit or risk of Contrave on cardiovascular risk" and that "[t]he[50% interim] results do not confirm cardiovascular benefits of Contrave claimed by Orexigen in the patent application based on the data obtained at the 25 percent time point in the trial." *Id.* He added that "[t]he inconsistency of effects on cardiovascular outcomes between the first 25 percent and the second 25 percent of the Light Study clearly illustrates the risks inherent in pre-judgment of clinical trial results based upon an interim analysis and demonstrate why interim results should remain confidential during any ongoing trial." *Id.* (emphasis omitted).

The Moving Defendants argue that the press release "did not correct anything said by Defendants on March 3" because it "said nothing about *who* was responsible for publishing the patent" and did not "dispute the claims contained therein," as "the 25 percent interim results were still technically accurate." Mot. at 20 (quoting *Khoja*, 899 F.3d at

1015). Lead Plaintiff notes that the Forbes.com article concerning the press release, published later that day, noted that "[p]atients were misled, investors were misled." Opp'n at 23–24 (quoting CC ¶ 127) (emphasis omitted).

Although Dr. Nissen's May 12, 2015 press release may have served as a corrective disclosure for the alleged misrepresentations made on May 8, 2015, the Court must agree with the Moving Defendants that it does not reveal any information about the alleged misrepresentations or omissions from March 3, 2015, that had not already been revealed to the market. The alleged misstatements on March 3, 2015, related solely to the unauthorized publication of the "unreliable" interim 25 percent data and Defendants' role in the publication of the '371 Patent. Articles published on March 3 through 5, 2015, however, already had made clear that Orexigen had published the interim 25 percent data without the authorization of the FDA and that the FDA considered the interim 25 percent data unreliable. *See supra* Section II.A.2.a. Consequently, Dr. Nissen's May 12, 2015 press release did not serve to "correct" any of those alleged misrepresentations, which had already been revealed to the market.

The only remaining question is whether Dr. Nissen's May 12, 2015 press release revealed to the market any information concerning the alleged omissions related to the publication of the '371 Patent. The Court concludes that it did not. The Ninth Circuit reasoned that, "by failing to inform investors about Orexigen's role in publishing the 2014 Patent Application, Orexigen arguably gave the false impression that it played no role in revealing the 25 percent interim results." *See Khoja*, 899 F.3d at 1013. The only information contained in the May 12, 2015 press release concerning the 2014 Patent Application is that, "in March 2015, Orexigen publicly disclosed the confidential 25 percent interim analysis of the Light Study as part of a patent and securities filing, without the authorization of the study's academic leadership." CC ¶ 126 (emphasis omitted). The March 5, 2015 alleged corrective disclosure, however, had already disclosed that "Orexigen ha[d] made the interim data from the LIGHT trial public through the process of obtaining patents," a decision that violated Orexigen's duty to keep such results

confidential in accordance with "FDA guidance[] and the scientific literature." *See* Defs.' RJN Ex. F. The Court therefore concludes that the May 12, 2015 press release was not a corrective disclosure as to the alleged misrepresentations from March 3, 2015.[7]

B. Third Cause of Action: Violations of § 20(a) of the 1934 Act Against the Moving Defendants

"Section 20(a) of the [1934] Act makes certain 'controlling' individuals also liable for violations of section 10(b) and its underlying regulations." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009), *as amended* (Feb. 10, 2009). Specifically, Section 20(a) provides:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable (including to the Commission in any action brought under paragraph (1) or (3) of section 78u(d) of this title), unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). "Thus, a defendant employee of a corporation who has violated the securities laws will be jointly and severally liable to the plaintiff, as long as the plaintiff demonstrates 'a primary violation of federal securities law' and that 'the defendant exercised actual power or control over the primary violator.'" *Zucco Partners*, 552 F.3d at 990 (quoting *Am. W. Holding Corp.*, 320 F.3d at 945) (citing *Paracor Fin., Inc. v. Gen. Elec. Capital Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996)). "Section 20(a) claims may be dismissed summarily . . . if a plaintiff fails to adequately plead a primary violation of section 10(b)." *Id.* (citing *In re VeriFone Sec. Litig.*, 11 F.3d 865, 872 (9th Cir. 1993); *In re Metawave Commc'ns Corp. Sec. Litig.*, 298 F. Supp. 2d 1056, 1087 (W.D. Wash. 2003)).

[7] To reiterate, the Court makes no determination as to whether the May 12, 2015 press release served as a corrective disclosure as to the alleged misrepresentations from May 8, 2015.

The Moving Defendants contend that "[b]ecause the Complaint fails to plead a primary violation of Section 10(b), the Section 20(a) claim also fails." Mot. at 20 n.16 (citing *Lipton v. PathoGenesis Corp.*, 284 F.3d 1027, 1035 n.15 (9th Cir. 2002); *Zucco Partners, LLC*, 552 F.3d at 990). Having concluded that Lead Plaintiff adequately alleges a cause of action for violation of Section 10(b) of the Exchange Act and Rule 10b-5(b), *see supra* pages 23–38, the Court **DENIES** the Moving Defendants' Motion as to Lead Plaintiff's third cause of action.

CONCLUSION

In light of the foregoing, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' RJN (ECF No. 98-15), **DENIES** Lead Plaintiff's RJN (ECF No. 103-1), and **GRANTS IN PART AND DENIES IN PART** the Moving Defendants' Motion (ECF No. 98), as detailed above. Lead Plaintiff **MAY FILE** an amended consolidated complaint within thirty (30) days of the date on which this Order is electronically docketed. *Should Lead Plaintiff fail to file an amended complaint by this date, this action will proceed on his surviving causes of action*.

IT IS SO ORDERED.

Dated: September 23, 2019

Janis L. Sammartino
Hon. Janis L. Sammartino
United States District Judge