UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHAWN SHANAWAZ,
Plaintiff,

-v-

INTELLIPHARMACEUTICS INTERNATIONAL INC., et al.,
Defendants.

17-CV-5761 (JPO)

OPINION AND ORDER

J. PAUL OETKEN, District Judge:

This is a putative shareholder class action consolidated from three related lawsuits brought against Intellipharmaceutics International Inc. ("IPCI") and two of its executives, Isa Odidi and Domenic Della Penna (collectively, "Defendants") based on their alleged violations of the Securities Exchange Act of 1934 ("Exchange Act"). The crux of the plaintiffs' allegations is that Defendants misled investors regarding the types of research and testing IPCI had performed on one of its products, and that plaintiffs' stock value dropped once the truth came to light.

On November 21, 2017, the Court consolidated the three actions and appointed David Ducharme, Sam Snyder, and Julia Ann Snyder as Lead Plaintiffs pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u–4(a). (Dkt. No. 23.) Lead Plaintiffs then filed an Amended Complaint on January 29, 2018, asserting claims under Sections 10(b) and 20(a) of the Exchange Act on behalf of all purchasers of Defendant IPCI's securities at allegedly artificially inflated prices. (Dkt. No. 25 ("AC") ¶¶ 1, 155, 162, 172.)

Before the Court is Defendants' motion to dismiss the Amended Complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). (Dkt. No. 29.) For the reasons that follow, Defendants' motion is granted in part and denied in part.

I. Factual Background

Unless otherwise noted, the facts discussed below are drawn from the Amended Complaint (Dkt. No. 25 ("AC")) and are assumed to be true for purposes of Defendants' motion to dismiss.

A. The Parties

Defendant IPCI is a publicly traded Canadian pharmaceutical company specializing in the research and development of controlled-release drugs, with a particular focus on abuse-deterrent opioids. (AC ¶¶ 23, 26.) At all times relevant to this action, Defendant Isa Odidi served as IPCI's Chief Executive Officer ("CEO") and Chief Scientific Officer ("CSO"), and Defendant Dominic Della Penna served as IPCI's Chief Financial Officer ("CFO"). (AC ¶¶ 24–25.) At issue in this case is one of IPCI's drugs, known as Rexista, which Lead Plaintiffs allege has been "a primary focus of IPCI's business." (AC ¶ 28.) Rexista was designed as an abuse-deterrent opioid tablet, and it was intended to capitalize on the growing market for opioids that are resistant to abuse. (*Id.*) The Amended Complaint alleges that Defendants made a number of misleading statements regarding the development of Rexista, and that Defendants' statements artificially inflated IPCI's stock price. (AC ¶¶ 5, 9.)

Lead Plaintiffs David Ducharme, Sam Snyder, and Julia Ann Snyder seek to represent a class of all those who purchased Defendant IPCI's securities during the period in which IPCI's stock was trading at artificially inflated prices (the "Class Period"). (AC ¶¶ 1, 155.) They allege that this Class Period spans from May 21, 2015, the day IPCI announced that it intended to accelerate the development of Rexista, to July 26, 2017, the day a Food and Drug Administration ("FDA") advisory committee voted to recommend denying IPCI's New Drug Application ("NDA") for Rexista. (AC ¶¶ 1, 9, 12.)

B. FDA Review Process and Rejection of IPCI's Rexista NDA

1. Overview of the FDA Review Process

The first step in the development and approval process for any new drug is the Investigation New Drug Application ("IND"), which describes a new drug's composition and manufacturing information obtained from initial testing. (AC ¶ 30.) The IND must be approved before any clinical trials are initiated on human subjects. (*Id*.) Once an IND is approved, a drug sponsor can commence clinical trials, which proceed in three phases. (AC ¶ 31.) Only upon completing all three phases of trials can a sponsor submit an NDA to the FDA to approve the commercialization of a new drug. (*Id.*)

Upon receipt of an NDA, the FDA first conducts a threshold review to confirm "that the NDA is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101(a). Once the FDA has accepted an NDA for substantive review, the FDA may refer the NDA to "advisory committees" of industry experts who provide guidance to the FDA on the NDA's sufficiency, as well as on proposed labeling. (AC ¶ 31.) If an NDA is denied, the FDA will send the applicant a Completed Response Letter outlining the NDA's deficiencies and, where possible, will provide recommendations for obtaining approval for any subsequent NDAs. (*Id.*)

2. The FDA's April 2015 Guidance for Abuse-Deterrent Opioids

In April 2015, the FDA published nonbinding guidance addressed to drug sponsors seeking approval for opioids with abuse-deterrent properties (the "Guidance"). (AC ¶ 32.)[1] The Guidance is "intended to assist sponsors who wish to develop opioid drug products with potentially abuse-deterrent properties" by describing the FDA's stance on the types of "studies

[1] In support of their motion to dismiss, Defendants attach a complete version of the Guidance. (Dkt. No. 30-1.)

[that] should be performed and evaluated. . . and their implications in product labeling." (*Id.*; *see also* Dkt. No. 30-1 at 1.) Though expressly disclaiming that it is intended to introduce new formal requirements for abuse-deterrent opioid drug applications (*id.*), the Guidance does provide an outline of the different types of studies that the FDA suggests it will look for when reviewing such applications (*see generally* Dkt. No. 30-1 at 4–17).

The Guidance recommends three particular categories of studies to manufacturers seeking to "obtain a full and scientifically rigorous understanding of the impact of a technology or technologies on a product's abuse potential." (AC ¶ 34.) The three categories of recommended studies are: (i) laboratory-based in vitro manipulation and extraction studies ("Category 1 studies"), designed to evaluate the ease with which a drug can be manipulated to evade its abuse-deterrent properties; (ii) pharmacokinetic studies ("Category 2 studies"), designed to evaluate the varying ways the drug would be processed by the user's body when taken intact or in manipulated form and in comparison with other drugs; and (iii) clinical abuse potential studies ("Category 3 studies"), designed to assess the impact of the drug's abuse-deterrent properties on actual using populations. (AC ¶¶ 35–36; *see also* Dkt. No. 30-1 at 6–10.)

The Guidance emphasizes the importance of the interplay among these three categories of studies. For example, the FDA indicated that "[t]he results of Category 1 studies may influence the design of Category 2 pharmacokinetic studies and Category 3 clinical abuse potential studies by suggesting the methods of manipulation that would yield the greatest release of opioid [and] [t]he results of Category 2 studies may influence the need for Category 3 studies of clinical abuse potential and the designs and goals of these studies." (AC ¶ 36; Dkt. No. 30-1 at 5.) The FDA suggests that, "in general, any development program for studying abuse-deterrent technologies should include data from all three categories of studies," but the Guidance allows that "there may

be exceptions" for specific products not feasibly abusable through certain methods. (Dkt. No. 30-1 at 5.)

The Guidance also recommends that manufacturers of abuse-deterrent opioids should evaluate their new drug with reference to each of three primary routes of abuse: oral, nasal, and intravenous ("IV"). (AC ¶ 4.) The Guidance emphasizes the need to review the interplay of a drug's deterrence mechanisms for each of these pathways, noting that "[t]he evaluation of an abuse-deterrent formulation should . . . anticipate the effect that deterring abuse by one route may have on shifting abuse to other, possibly riskier route[s]." (AC ¶ 33.) The FDA suggests that studies geared towards different routes of abuse would be especially important for those drugs susceptible to abuse via multiple pathways, because the development of abuse-deterrent mechanisms for only one pathway could lead to greater risk of abuse via other pathways; at the same time, the FDA recognizes that studies regarding abuse deterrence are sometimes unnecessary where certain drugs are unlikely to be abused via pathways. (Dkt. No. 30-1 at 4–5.)

3. The FDA's Rejection of the Rexista NDA

IPCI submitted an IND for Rexista on March 30, 2015, approximately eight weeks before the start of the Class Period. (AC ¶ 40.) In line with industry practice, executives from IPCI met with the FDA around this time to discuss the types of studies and data required for the eventual Rexista NDA. (AC ¶ 38.)

On May 21, 2015, the first day of the Class Period, IPCI announced plans to expedite the development timeline for Rexista in light of positive feedback from the FDA regarding Rexista's IND. (AC ¶ 41.) On November 25, 2016, IPCI announced that it had submitted an NDA for Rexista to the FDA. (AC ¶ 44.) On February 27, 2017, IPCI announced that the FDA had accepted the Rexista NDA for substantive review. (AC ¶ 46.) The FDA subsequently scheduled

an advisory committee meeting regarding the Rexista NDA for July 26, 2017, the last day of the Class Period. (*Id*.)

The FDA generally releases background materials regarding the content of an NDA no later than two business days prior to any advisory committee meeting. (AC ¶ 50 n.9.) In accordance with this policy, the FDA published background materials for the Rexista NDA on July 24, 2017. (AC ¶ 50.)[2] These materials revealed publicly for the first time the scope of research and data included in IPCI's Rexista NDA. (*Id.*) With respect to compliance with the Guidance, the background materials revealed that the NDA contained only Category 1 studies relating exclusively to Rexista's capacity to deter abuse via the IV route, but not any Category 2 or Category 3 studies or any studies regarding Rexista's susceptibility to oral and nasal abuse. (*Id*.)

On July 26, 2017, the advisory committee convened to review the Rexista NDA voted overwhelmingly against its approval, largely due to the NDA's noncompliance with the FDA's Guidance. (AC ¶¶ 56–57.)[3] As the chairperson of the committee summarized following the committee's first voice vote, "[t]he panel believes, and I believe, that the guidelines need to be followed. I think the committee feels uncomfortable in providing a signal that it's all right to present incomplete data and expect a positive outcome." (AC ¶ 57.) Similarly, the chairperson summarized the assessment of the committee following a later voice vote "by saying that the sense of the group is that it's not acceptable to predict intranasal or oral abuse deterrent effects

[2] In support of their motion to dismiss, Defendants attach complete versions these background materials. (Dkt. Nos. 30-2, 30-3.)

[3] The advisory committee convened to review the Rexista NDA was a "Joint Meeting of the Anesthetic and Analgesic Drug Products and Drug Safety and Risk Management Advisory Committees." (AC ¶ 55.) In support of their motion to dismiss, Defendants attach the complete transcript from the July 26, 2017 advisory committee meeting. (Dkt. No. 30-4.)

from category 1 studies alone for this product and that the best way to evaluate for the deterrent effects is to actually use the guidances [sic] provided by the FDA, which is crystal clear on this." (Dkt. No. 30-4 at 290.)

Consistent with these summaries, many of the individual committee members who opted to explain their votes on the record also emphasized the extent of the Rexista NDA's noncompliance with the FDA's Guidance, and in particular the insufficiency of an NDA for an abuse-deterrent opioid including only Category 1 studies with respect to only one route of abuse. (*See, e.g.* AC ¶¶ 58–63; Dkt. No. 30-4 at 266 ("I am uncomfortable with the idea that we would be putting a product out that is potentially . . . going to deter IV drug abuse, . . . and we have no knowledge about whether it really provides any deterrent for abuse by those other routes."); Dkt. No. 30-4 at 279 ("So I think that the initial question, whether category 1 studies can assess the effects, I think is clearly answered with no."); Dkt. No. 30-4 at 287 ("I agree that category 2 and 3 studies would be crucial here.").) Given the extent of the Rexista NDA's noncompliance with the Guidance, one committee member asked an FDA representative present at the meeting whether the FDA had given indications that noncompliance with the Guidance would be acceptable to the FDA, to which the representative responded "[n]o, we provide advice that's consistent with the guidance." (AC ¶ 58.)

On September 25, 2017, IPCI announced it had received a Complete Response Letter from the FDA confirming that the FDA would be denying the Rexista NDA. (AC ¶ 64.) According to IPCI, and consistent with the advisory committee's recommendations, the FDA recommended that IPCI "complete the relevant Category 2 and Category 3 studies to assess the abuse-deterrent properties of [Rexista] by the oral and nasal routes of administration" prior to submitting any revised NDA for Rexista. (*Id.*)

C. IPCI's Allegedly Misleading Statements

The Amended Complaint identifies twenty-four allegedly misleading statements made by Defendants. (AC ¶¶ 67–110; Dkt. No. 31 at 9–10.) The statements, each of which was issued in the period leading up the FDA's denial of the Rexista NDA, consist mainly of Defendants' public descriptions of Rexista's features and development status, as well as the content of the Rexista NDA and its prospects for FDA approval.[4] Despite the large number of statements at issue, the parties each describe the Amended Complaint as alleging three general types of misrepresentations. (*See* Dkt. No. 31 at 14–20; Dkt. No. 33 at 11–21.)

The first type of misrepresentation alleged in the Amended Complaint concerns Defendants' statements describing the content and scope of studies included in the Rexista NDA. (*See, e.g.,* AC ¶ 95 ("The submission also includes a comprehensive array of abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of drug by oral, intra-nasal and intravenous pathways, having reference to the FDA's 'Abuse-Deterrent Opioids – Evaluation and Labelling' guidance published in April 2015."); *see also* AC ¶¶ 97, 100, 103, 107, 110.) The Amended Complaint alleges that these statements were false and misleading because Rexista's NDA in truth did not include any studies relating to the drug's capacity for

[4] These statements were issued in the period spanning from May 21, 2015, which was the date IPCI announced its intention to expedite the development of Rexista, through July 11, 2017, which was approximately two weeks prior to the FDA's release of the background materials that made public the true content of IPCI's NDA for Rexista. (AC ¶¶ 67, 109, 112.) The statements were mostly issued as part of Securities and Exchange Commission ("SEC") filings and their attachments (*see, e.g.* AC ¶¶ 67, 69, 72, 75, 77, 79, 82, 85, 88, 93, 95, 97, 99, 102, 107, 110), save for two of the statements, which were issued as part of publicly disseminated interviews with securities analysts (*see, e.g.*, AC ¶¶ 91, 105). In support of their motion to dismiss, Defendants attach complete versions of a number of these statements. (Dkt. Nos. 30-5, 30-6, 30-7, 30-8, 30-9, 30-10, 30-11, 30-12, 30-13.)

abuse via the oral or nasal pathways or any Category 2 or Category 3 studies as suggested by the Guidance. (*See, e.g.*, AC ¶ 108.)

The second type of misrepresentation alleged in the Amended Complaint concerns Defendants' statements describing Rexista's "bioequivalence" to OcyContin.[5] (*See, e.g.*, AC ¶ 67 ("The . . . FDA stated that the Company will not be required to conduct Phase III studies if bioequivalence to Oxycontin™ is demonstrated. . . . The Company believes . . . [this] provides a basis for an accelerated development plan . . . without the need for more . . . studies."); AC ¶ 77 ("We take great pride in being the first pharmaceutical company, to the best of our knowledge, to have demonstrated bioequivalence . . . [to] Oxycontin®. This enables us to accelerate the development and commercialization of our abuse deterrent Rexista™ Oxycodone XR product. . . ."); *see also* AC ¶¶ 70, 73, 81, 83, 86, 103, 107.) The Amended Complaint alleges that these statements were false and misleading because IPCI had not conducted studies demonstrating Rexista's bioequivalence to Oxycontin in accordance with the Guidance. (*See, e.g.*, AC ¶ 87.)

The third type of misrepresentation described in the Amended Complaint relates to Defendants' descriptions of Rexista's oral and nasal abuse-deterrent properties. (*See, e.g.*, AC ¶ 86 ("Our Rexista Oxycodone XR formulation contains a blue dye that is emitted once the tablet is tampered with or crushed. The stigmatizing blue dye acts as a deterrent if abused orally or via the intra-nasal route."); AC ¶ 91 ("Rexista™ has a number of abuse-deterrent properties that not only match but exceed those of both currently marketed products and products in late-stage development. These properties address mitigating abuse via methods of tampering, such as

[5] According to the Amended Complaint, two drugs may be said to be "bioequivalent" when they have sufficiently similar biological properties to allow the sponsor of a new drug to rely on studies performed on the other bioequivalent drug without repeating them. (AC ¶ 40 n.8.)

[listing methods], and via methods of administration, such as [listing methods]."); *see also* AC ¶¶ 80, 83, 89, 93, 103, 110).) The Amended Complaint alleges that these statements were false and misleading when made because IPCI "had not conducted all studies in accordance with the 2015 FDA Guidance necessary to demonstrate that the Company's formulation of Rexista possessed the foregoing abuse-deterrent properties." (AC ¶ 94.) More particularly, the Amended Complaint alleges that IPCI "did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes." (*Id.*)

D. Scienter Allegations

The Amended Complaint alleges a number of facts to establish that Defendants acted with the requisite scienter in issuing these misrepresentations. For example, the Amended Complaint describes Rexista's central importance to IPCI's business portfolio and the tight-knit manner in which IPCI's business was run, as well as Defendants' SEC-imposed reporting obligations and their duties to disseminate truthful information. (AC ¶¶ 142–48.) With respect to the FDA's Guidance, the Amended Complaint cites a number of statements in which Defendants described the Rexista NDA with reference to the Guidance to show that Defendants knew the content of the Guidance and that their compliance with the Guidance was not what they publicly represented it to be. (AC ¶¶ 116–17.)

The Amended Complaint also cites evidence demonstrating that Defendants had a motive to mislead the market regarding Rexista. The Amended Complaint describes IPCI's dependence on sales of its stock in order to cover its operating losses, as well as the correlation between Rexista's expedited development and IPCI's increased stock prices, as together producing a strong financial motive for IPCI to mislead the market about Rexista. (AC ¶¶ 125–31.) The Amended Complaint also describes Defendants Odidi and Della Penna's incentive packages,

which were tied to IPCI's stock price and, for Odidi, to the rate at which IPCI generated NDAs for FDA review, regardless of FDA approval. (AC ¶¶ 119–24.)

Finally, with respect to Defendant Odidi in particular, the Amended Complaint describes his suspiciously timed sales of his IPCI stock early in the Class Period and his founding of a new Chinese pharmaceutical venture around the period in which the FDA denied the Rexista NDA as indicative of his awareness that the Rexista NDA was not as publicly represented. (AC ¶¶ 132–41.) In addition, the Amended Complaint alleges that Odidi, who had a Ph.D. in Pharmaceutics, was generally responsible for the review of all IPCI NDAs prior to their submission to the FDA, and that he played a particularly active role in preparing the Rexista NDA given its importance to IPCI. (AC ¶¶ 39, 143.)

II. Procedural Background

This action was filed on July 28, 2017. (Dkt. No. 1.) The Court issued an Order appointing Lead Plaintiffs on November 21, 2017 (Dkt. No. 23), and Lead Plaintiffs filed an Amended Complaint on January 29, 2018 (Dkt. No. 25). Now before the Court is Defendants' March 30, 2018 motion to dismiss the Amended Complaint. (Dkt. No. 29.)

III. Legal Standards

To survive a motion to dismiss brought pursuant to Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter . . . to state a claim to relief that is plausible on its face." *Wilson v. Merrill Lynch & Co, Inc.*, 671 F.3d 120, 128 (2d Cir. 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). A claim is facially plausible where it permits "the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In evaluating a Rule 12(b)(6) motion to dismiss, "[t]he Court must accept as true all well-pleaded factual allegations in the complaint, and 'draw [ ] all inferences in the plaintiff's favor.'" *Goonan v. Fed. Reserve Bank of New York*, 916 F.

Supp. 2d 470, 478 (S.D.N.Y. 2013) (quoting *Allaire Corp. v. Okumus*, 433 F.3d 248, 249–50 (2d Cir. 2006)). In addition to the complaint's factual allegations, courts may also "consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

Securities fraud claims are subject to the heightened pleading standards established by Federal Rule of Civil Procedure 9(b) and the PSLRA, 15 U.S.C. § 78u-4. *Id*. at 99. Rule 9(b) provides that claims alleging fraud "must state with particularity the circumstances constituting fraud or mistake." To satisfy this standard in cases alleging securities fraud based on a misstatement, a complaint must specifically identify the allegedly fraudulent statement, the speaker, the place and time the statement was made, and the reason the statement was fraudulent. *ATSI Commc'ns*, 493 F.3d at 99. The PSLRA similarly requires plaintiffs bringing fraud claims under federal securities law to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).

In addition, the PSLRA requires that a federal securities fraud plaintiff "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id*. § 78u-4(b)(2)(A). The Supreme Court has explained that to qualify "as 'strong' within the intendment of [the PSLRA], . . . an inference of scienter must be more than merely plausible or reasonable—it must be 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).

IV. Discussion

Lead Plaintiffs bring suit under the Exchange Act and SEC Rules promulgated thereunder. 15 U.S.C. § 78j(b); 15 U.S.C. § 78t(a); 17 C.F.R. § 240.10b-5. They assert two claims: (1) a securities fraud claim pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 against all three Defendants; and (2) a control person claim pursuant to Section 20(a) of the Exchange Act against Defendants Odidi and Della Penna. (AC ¶¶ 162, 172.) Defendants move to dismiss both of Lead Plaintiffs' claims. (Dkt. No. 31 at 12, 28.) The Court addresses each in turn.

A. Section 10(b) Claims

The elements of Lead Plaintiffs' Section 10(b) claims are: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (quoting *Stoneridge Inv. Partners, LLC v. Scientific–Atlanta, Inc.*, 552 U.S. 148, 157 (2008)).

Defendants move to dismiss based on elements one and two of these claims, contesting whether their statements constituted material misrepresentations or omissions, and whether they made the statements with the requisite level of scienter. (Dkt. No. 31 at 13, 23.)

Statements may constitute actionable misrepresentations under Section 10(b) if they include "any untrue statement of a material fact or [omit] . . . a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." *ECA and Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 197 (2d Cir. 2009) (quoting 17 C.F.R. § 240.10b–5(b) (2008)). "[S]tatements of fact are actionable if they are materially misleading." *Menaldi v. Och–Ziff Capital Mgmt. Grp.*

LLC, 164 F. Supp. 3d 568, 583 (S.D.N.Y. 2016). "The test for whether a statement is materially misleading under Section 10(b) is not whether the statement is misleading in and of itself, but whether the defendants' representations, *taken together and in context*, would have misled a reasonable investor." *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 250 (2d Cir. 2016) (internal quotation marks omitted). Statements of opinion may also constitute misrepresentations where: (1) "the speaker did not hold the belief she professed"; (2) "the supporting fact [the speaker] supplied were untrue"; or (3) "the speaker omits information whose omission makes the statement misleading to a reasonable investor." *In re Inv. Tech. Group, Inc. Sec. Lit.*, 251 F. Supp. 3d 596, 618 (S.D.N.Y. 2017) (alterations in original) (quoting *Tongue v. Sanofi*, 816 F.3d 199, 209–10 (2d Cir. 2016)).

The requisite level of scienter required for Lead Plaintiffs' Section 10(b) claims is one "embracing intent to deceive, manipulate, or defraud." *Tellabs,* 551 U.S. at 319 (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193–194 n.12 (1976)). The Second Circuit has allowed that a "plaintiff may satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI Commc'ns*, 493 F.3d at 99. In the context of Section 10(b), recklessness is "a state of mind approximating actual intent, and not merely a heightened form of negligence." *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) (citation and emphasis omitted). Such reckless conduct must be "'highly unreasonable'" and "'an extreme departure from the standards of ordinary care.'" *Novak v. Kasaks,* 216 F.3d 300, 308 (2d Cir. 2000) (quoting *Rolf v. Blyth, Eastman Dillon & Co.*, 570 F.2d 38, 47 (2d Cir.1978)).

In briefing Defendants' motion to dismiss, the parties focus their analysis around the three general types of misrepresentations described in the Amended Complaint. (*See* Dkt. No. 31 at 14–20; Dkt. No. 33 at 11–21.) The Court does the same.

1. Statements Regarding the Content of the Rexista NDA

The first type of misrepresentation alleged in the Amended Complaint involves Defendants' descriptions of the content of the Rexista NDA that was filed with the FDA. Lead Plaintiffs identify eight such statements in the Amended Complaint. (*See generally* Dkt. No. 33 at 11.) In the first of those statements, which was issued on November 25, 2016, Defendants allegedly represented that the Rexista NDA included "a comprehensive array of abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of drug [sic] by oral, intra-nasal and intravenous pathways, having reference to the FDA's 'Abuse-Deterrent Opioids – Evaluation and Labelling' guidance published in April 2015." (AC ¶ 95.) In the other seven statements, all of which were issued between February 2, 2017 and July 11, 2017, Defendants are alleged to have represented that the Rexista NDA included "abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of the drug by various pathways, including oral, intra-nasal and intravenous, having reference to the FDA's 'Abuse-Deterrent Opioids —Evaluation and Labelling' guidance published in April 2015." (AC ¶¶ 97, 100, 102–3, 107, 109.) All of these statements were issued after IPCI had already completed and filed the Rexista NDA with the FDA. (AC ¶ 44.)

a. Misrepresentation

Defendants' public statements during the Class Period describing the contents of the Rexista NDA are directly contradicted by the true contents of the Rexista NDA. Accordingly, the Court concludes that these statements may constitute actionable misrepresentations.

For example, contrary to Defendants' public statements that the Rexista NDA included "studies . . . related to abuse of drug [sic] by oral, intra-nasal and intravenous pathways" (AC ¶ 95), the FDA later revealed that the "abuse-deterrent features of [Rexista] for the oral and intranasal routes . . . [had] not been formally evaluated" in the NDA (AC ¶ 50; *see also* Dkt. No. 30-2 at 8, 21; Dkt. No. 30-4 at 43). Similarly, contrary to Defendants' public statements that the NDA included studies necessary "to support abuse-deterrent label claims" for the "oral, intra-nasal *and* intravenous pathways" (AC ¶ 95 (emphasis added)), the Rexista NDA in fact sought "abuse-deterrent labeling only for the IV route of abuse" and did not include the studies "required for abuse-deterrent labeling incorporating Category 2 (pharmacokinetic [PK]) or Category 3 (pharmacodynamic [PD]) claims for the oral and intranasal routes" (AC ¶ 50). Defendants' alleged public representations that the Rexista NDA contained studies necessary to support nasal and oral abuse-deterrent labelling were thus false when made, and accordingly, these statements may constitute actionable representations.

The same conclusion is warranted with respect to the portions of these statements in which Defendants represented that the NDA was submitted with "reference to the FDA's 'Abuse-Deterrent Opioids—Evaluation and Labelling' guidance published in April 2015." (*See, e.g.*, AC ¶ 95.) The context in which these statements were issued, namely as part of press releases also describing Rexista's "suite of abuse-deterrent features and overdose prevention technologies," would plausibly have led a reasonable investor to believe that Defendants had

fully complied with the terms of Guidance to the extent necessary to obtain such a suite of abuse-deterrent labeling. (*Id*.) Defendants' other statements from the Class Period, for example their suggestion that it was their "goal to receive all three allowable deterrent claims for Rexista," would only have buttressed such a conclusion. (AC ¶ 105.) And the Amended Complaint includes the assessment of a contemporary investment analyst who understood Defendants' statements in just such a way. (AC ¶ 45.) Yet despite these statements, the NDA in fact contained none of the Category 2 and Category 3 recommended by the Guidance to manufacturers seeking such a broad spectrum of abuse-deterrent labeling. (AC ¶ 50.) Accordingly, Defendants' statements describing the scope of the NDA's compliance with the terms of the Guidance may also subject Defendants to Section 10(b) liability.

Defendants contest this conclusion. In doing so, Defendants attempt to construe Lead Plaintiffs' claims based on these statements as "fraud by hindsight." (Dkt. No. 31 at 13–14.) To support this contention, Defendants cite cases in which courts have held that a party's failure to obtain FDA approval for a drug does not render earlier statements actionable for expressing optimism about that drug's prospects before the FDA. *See, e.g.*, *In re AstraZeneca Sec. Lit.*, 559 F. Supp. 2d 453, 470–71 (S.D.N.Y. 2008); *Sanofi*, 816 F.3d at 213–14.

Defendants misconstrue Lead Plaintiffs' allegations. At issue here are not Defendants' opinions about the NDA's prospects before the FDA, but Defendants' allegedly false descriptions of the contents of the NDA itself. This case is thus unlike those in which a drug manufacturer is alleged to have "stated [an] opinion about [a drug's] trial results . . . [and] the FDA disagreed with Defendants' interpretation of the data." *Sanofi*, 816 F.3d at 214. Instead, Lead Plaintiffs here allege that there was no such data to interpret, because IPCI never even performed or submitted the described studies to the FDA, despite having told the public

otherwise. (*See, e.g.*, AC ¶ 96.) These types of misstatements may constitute actionable misrepresentations under Section 10(b). *See, e.g.*, *In re CytRx Corp. Sec. Lit.*, No. 16 Civ. 5519, 2017 WL 5643161, at *7 (C.D. Cal. Aug. 14, 2017) (upholding Section 10(b) claim because a "Defendants' statement that the Trial was being conducted under [a non-binding FDA protocol], while concurrently violating the [protocol's] assumptions, was misleading.")

Defendants also argue that their choice to pursue abuse-deterrent labeling for only the IV route of abuse on the basis of only Category 1 studies was not in fact inconsistent with the terms of the non-binding Guidance. (Dkt. No. 31 at 14–16.) As an initial matter, the Court notes that the facts Defendants point to in support of this contention are mostly unpersuasive. Defendants cite the FDA's approval of another drug on the basis of only *in vitro* (i.e. Category 1) studies, but that drug was approved prior to the issuance of the Guidance. (Dkt. No. 30-14.) Defendants point to a question from the FDA representative to the advisory committee asking the committee to consider Rexista for only IV abuse-deterrence labeling (Dkt. No. 30-4 at 296), but they neglect to mention that the same FDA representative had earlier disclaimed that such labeling was consistent with the Guidance (Dkt. No. 30-4 at 249) and that the advisory committee nearly unanimously voted to reject such labeling on the basis of the Guidance (AC ¶¶ 56–57). And Defendants suggest that the FDA's acceptance of the NDA for substantive review was indicative of the NDA's substantive sufficiency, despite the regulations governing the FDA's initial acceptance of NDAs being largely concerned with administrative sufficiency, 21 C.F.R. § 314.101(a), and despite the FDA's ultimate rejection of the NDA being based on substantive grounds for non-compliance with the Guidance (AC ¶ 64).

Still, irrespective of the weight of this evidence, it is all largely tangential to Lead Plaintiffs' allegations. Whether or not the FDA or the terms of the Guidance *could* have allowed

Defendants to obtain abuse-deterrent labeling for IV abuse alone based only on Category 1 studies, Defendants chose to publicly represent that their NDA in fact included other types of studies that it did not in fact contain. Because Lead Plaintiffs plausibly allege that these descriptions of the actual contents of the NDA were false when made, these statements may constitute actionable misrepresentations for purposes of Section 10(b) liability.

b. Scienter

The Amended Complaint provides "strong circumstantial evidence of conscious misbehavior or recklessness," *ATSI*, 493 F.3d at 99, because it includes evidence showing that Defendants had "knowledge of facts or access to information contradicting their public statements," *Novak*, 216 F.3d at 308. IPCI, as the sponsor of the Rexista NDA and the party responsible for drafting and preparing the submission, can be presumed to have known the contents of the NDA at the time it issued the relevant public statements. (*See, e.g.*, AC ¶¶ 40, 44; *see generally* Dkt. No. 30-2.) Moreover, IPCI also described Rexista as central to its business and as the primary focus of its research and development during the Class Period, buttressing the plausibility of Lead Plaintiffs' claim that IPCI was or should have been aware of the contents of the NDA at the times of the misrepresentations. (*See, e.g.*, AC ¶¶ 27–28, 142.)

With respect to the individual Defendants, the Amended Complaint includes statements from anonymous former IPCI employees describing in detail the personal involvement of Defendants Odidi and Della Penna in the development of the Rexista NDA. (AC ¶¶ 38–39.) Defendants Odidi and Della Donna are also regularly quoted on behalf of IPCI throughout the Amended Complaint as describing the attributes of Rexista and the contents of the Rexista NDA. (*See, e.g.*, AC ¶¶ 91, 95, 97, 102–03.) If, as Lead Plaintiffs allege, these two Defendants were actively involved in the development and submission of the Rexista NDA to the FDA, they also

can be presumed to have known the contents of the NDA at the time they issued the relevant public statements falsely describing the NDA's contents. Thus taking Lead Plaintiffs' alleged facts as true, they establish that these Defendants "knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." *Novak*, 216 F.3d at 308. Similar allegations have been found sufficient to support scienter for fraud claims premised on a drug manufacturer's misrepresentations about the contents of FDA filings. *See, e.g.*, *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 349–50 (E.D. Pa. 2014).

The Amended Complaint also makes a strong "showing that the defendants had both motive and opportunity to commit the fraud." *ATSI*, 493 F.3d at 99. With respect to opportunity, the Amended Complaint describes in detail Defendants' control over both the development of Rexista and the content of IPCI's public statements about Rexista. (AC ¶¶ 142–48.) The Amended Complaint paints a sufficiently plausible picture of each Defendant's motives to publicly misrepresent the content of Rexista's NDA as well: It describes IPCI's dependence on sales of its stock to cover its operating losses, as well as the correlation between Rexista's expedited development and IPCI's increased stock prices (AC ¶¶ 125–31); and it describes Defendants Odidi and Della Penna's incentive packages, which were tied to IPCI's stock price, and for Odidi, the rate at which IPCI generated NDAs for FDA review, regardless of FDA approval (AC ¶¶ 119–24).

Defendants contest the weight of Lead Plaintiffs' motive evidence, asserting that this evidence paints a picture of typical pharmaceutical business practices and executive incentive packages. (Dkt. No. 31 at 26–27.) The Court need not evaluate whether each of the various motives described in Amended Complaint and attributed to each of the three Defendants constitute "[m]otives that are common to most corporate officers, such as the desire for the

corporation to appear profitable and the desire to keep stock prices high to increase officer compensation," *ECA, Local 134*, 553 F.3d at 198, because the question before the Court now is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 324. Here, viewing Lead Plaintiffs' motive evidence in conjunction with their evidence depicting Defendants' central roles in Rexista's development, the drafting of its NDA, and Defendants' repeated issuance of public statements at odds with the true contents of that NDA, the Court concludes that "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id*. Accordingly, Lead Plaintiffs have satisfied the scienter pleading requirements for their Section 10(b) claims based on those statements involving the contents of the Rexista NDA filed with the FDA. These claims thus survive Defendants' motion to dismiss.

2. Statements Regarding Rexista's Bioequivalence to OxyContin

The second type of misrepresentation alleged in the Amended Complaint involves Defendants' descriptions of Rexista's bioequivalence to OxyContin. Lead Plaintiffs identify eleven such statements in the Amended Complaint. (*See generally* Dkt. No. 33 at 18.) In the first of those statements, which was issued on May 21, 2015, Defendants are alleged to have represented that they had received a "notification from the FDA [which] stated that the Company [would] not be required to conduct Phase III studies if bioequivalence to Oxycontin™ is demonstrated," a notification which "enable[d IPCI] to accelerate the development and commercialization of [its] abuse deterrent Rexista™ Oxycodone XR product candidate." (AC ¶ 67.) Lead Plaintiffs identify three other similar statements in their Amended Complaint. (AC ¶¶ 69, 72, 80.) Lead Plaintiffs also identify three statements in which Defendants

represented that they had successfully demonstrated Rexista's bioequivalence to OxyContin, including the following statement:

> We take great pride in being the first pharmaceutical company, to the best of our knowledge, to have demonstrated bioequivalence in both fasted and fed conditions to the brand reference drug Oxycontin®. This enables us to accelerate the development and commercialization of our abuse deterrent Rexista™ Oxycodone XR product candidate without the need for costly and time-consuming Phase III efficacy trials.

(AC ¶ 77; *see also* AC ¶¶ 82, 85 ("Having now demonstrated such bioequivalence, we believe we will not be required to conduct Phase III studies although no assurance can be given. . . .").) Finally, Lead Plaintiffs identify four statements in which Defendants described the Rexista NDA as being "supported by pivotal pharmacokinetic studies that demonstrated that Rexista is bioequivalent to OxyContin." (AC ¶¶ 102–03; 107.) The last of these statements was issued on June 30, 2017. (*See* AC ¶ 107.)

Contrary to Lead Plaintiffs' allegations, the full versions of the documents cited in Lead Plaintiffs' Amended Complaint reveal that IPCI did in fact conduct studies to demonstrate Rexista's bioequivalence to OxyContin, and that IPCI did include these studies in the Rexista NDA. (*See* Dkt. No. 30-2 at 9–11, 24–26; Dkt. No. 30-3 at 101–04; Dkt. No. 30-4 at 53–56.) While Lead Plaintiffs emphasize one advisory committee member's expressed skepticism as to the results of the bioequivalence studies (AC ¶ 59), there is no indication that that committee member's opinion was shared by the FDA or other committee members. Though a number of committee members questioned IPCI about the structure and methodologies IPCI used for its bioequivalence studies (*see, e.g.*, Dkt. No. 30-4 at 84–85, 156–57; 163–65, 171–72), no other committee member saw fit to cite flaws with these studies when voting to deny the Rexista NDA, and Lead Plaintiffs do not allege that IPCI's failure to demonstrate bioequivalency factored into the FDA's ultimate decision to deny approval of the Rexista NDA. (AC ¶ 64.) In

any event, any FDA skepticism as to the results of these studies would not render false or misleading Defendants' assertions that these studies had in fact been conducted and submitted to the FDA. *See Sanofi*, 816 F.3d at 214 ("Defendants' statements were not misleading simply because the FDA disagreed with Defendants' interpretation of the data."). Accordingly, Defendants' statements representing that they had submitted to the FDA bioequivalency studies for Rexista and OxyContin were true when made and thus are not actionable under Section 10(b).

Similarly, Defendants' statements opining on the results of these studies are non-actionable opinions. Section 10(b) claims premised on a party's statements of opinion may survive only where: (1) "the speaker did not hold the belief she professed"; (2) "the supporting fact [the speaker] supplied were untrue"; or (3) "the speaker omits information whose omission makes the statement misleading to a reasonable investor." *In re Inv. Tech. Group*, 251 F. Supp. 3d at 618 (citing *Sanofi*, 816 F.3d at 209–10). Lead Plaintiffs assert that "Defendants lacked a reasonable basis to represent that bioequivalence to OxyContin had in fact been demonstrated" (Dkt. No. 33 at 19), but their assertion is rebutted by the number of different studies supporting bioequivalency that Defendants in fact performed and included in the Rexista NDA. (*See* Dkt. No. 30-2 at 9–11, 24–26; Dkt. No. 30-3 at 101–04; Dkt. No. 30-4 at 53–56, 84–85, 156–57; 163–65, 171–72.) Because Defendants did have meaningful scientific data to support their opinions about Rexista's bioequivalence to OxyContin, Lead Plaintiffs' Section 10(b) claims based on these opinions involve "little more than a dispute about the proper interpretation of data, a dispute [the Second Circuit has] rejected as a basis for liability." *Sanofi*, 816 F.3d at 214.

Accordingly, Defendants' statements describing Rexista's bioequivalence to OxyContin and their opinions about their bioequivalency studies are not actionable misstatements under Section 10(b), and Lead Plaintiffs' Section 10(b) claims premised on these statements must be dismissed.

3. Statements Regarding Rexista's Oral and Nasal Abuse-Deterrence Properties

The third type of misrepresentation alleged in the Amended Complaint involves Defendants' descriptions of Rexista's abuse-deterrent features for oral and nasal abuse. There are nineteen such statements in the Amended Complaint. (*See generally* AC ¶¶ 73, 75, 80, 83, 86, 89, 91, 93, 95, 97, 103, 107, 110.) Most of these statements described Rexista's abuse-deterrent features in broad terms, explaining generally that Rexista had a number of features "intended to present a significant barrier to tampering when subjected to various forms of anticipated physical and chemical manipulation commonly used by abusers." (AC ¶¶ 73, 80, 83, 86, 89, 93, 103, 107, 110.) Lead Plaintiffs also highlight as misleading two of the specific abuse-deterrent features described in many of these statements: (1) Rexista's resistance to alcohol dose-dumping, a method of abuse by which users combine opioid medications with alcohol to accelerate their blood stream's intake of the opioid; and (2) Rexista's "stigmatizing blue dye," which Defendants represented was capable of deterring oral and nasal abuse by staining those who tampered with the drug prior to oral and nasal abuse. (*See, e.g.*, AC ¶¶ 80, 83, 86, 89, 91, 93, 103, 107, 110.)

The full versions of the documents cited in Lead Plaintiffs' Amended Complaint reveal that Rexista did in fact have the features described in these statements. For example, the Rexista NDA contained Category 1 *in vitro* studies demonstrating Rexista's resistance to alcohol dose dumping and the difficulty users would face in removing the drug's blue dye once released.

(Dkt. No. 30-2 at 13–14, 21, 32.) These studies also provide support for Defendants' statements of opinion regarding these features' potential to deter abuse.

It is true that the advisory committee questioned Defendants' choice to study these abuse-deterrent features using only Category 1 studies and not to seek labeling for these abuse-deterrent capacities—but nowhere did the committee question that the drug in fact *had* these features. In fact, for some committee members, it was the very presence of these features that sparked worries over approving the drug without Category 2 and 3 studies to support oral and nasal abuse-deterrent labeling. (*See, e.g.*, AC ¶¶ 59, 62; *see also* Dkt. No. 30-4 at 255–56; 259–60; 264.)

Whether Defendants adequately studied the effectiveness of their drug's oral and nasal abuse-deterrent features is "a dispute about the proper interpretation of data." *Sanofi*, 816 F.3d at 214. The FDA's ultimate determination that Defendants had failed to adequately study these features in accordance with the Guidance does not render Defendants' statements merely describing the presence of these features or their opinions about these features false. Accordingly, Defendants' motion to dismiss Lead Plaintiffs' Section 10(b) claims that are premised on Defendants' descriptions of Rexista's oral and nasal abuse-deterrent features is granted.

B. Section 20(a) Claims

The elements of Lead Plaintiffs' Section 20(a) claims are: "(1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI Commc'ns*, 493 F.3d at 108. Defendants move to dismiss Lead Plaintiffs' Section 20(a) claims against Defendants Odidi and Della Penna on the basis of elements one and three. (Dkt. No. 31 at 28.)

As explained above, Lead Plaintiffs have successfully pleaded a primary violation of Section 10(b) by a controlled person, namely IPCI, with respect to IPCI's statements describing the contents of the Rexista NDA. *See supra* Section IV.A.1. Accordingly, Lead Plaintiffs have pleaded the first element of control person liability for these statements. Similarly, the same facts that were sufficient to establish that Defendants Odidi and Della Penna acted knowingly when disseminating false information about the contents Rexista NDA would also be sufficient to establish that each of them was, "in some meaningful sense, a culpable participant in the controlled person's fraud." *See ATSI Commc'ns*, 493 F.3d at 108. *See also In re Inv. Tech. Group Inc. Sec. Lit.*, 251 F. Supp. 3d at 624 ("As explained above [in Section 10(b) context], Plaintiff adequately alleges that [Defendant] acted with knowledge that the actionable statements were not accurate, thereby satisfying the culpable participation element."). Accordingly, Defendants' motion to dismiss Lead Plaintiffs' Section 20(a) claims based on IPCI's statements regarding the contents of the Rexista NDA is denied.

In contrast, because the Court has resolved to dismiss Lead Plaintiffs' Section 10(b) claims premised on Defendants' statements describing Rexista's abuse-deterrent features and its bioequivalency to OxyContin, Defendants' motion to dismiss Lead Plaintiffs' Section 20(a) claims based on these statements is granted.

V. Conclusion

For the foregoing reasons, Defendants' motion to dismiss is GRANTED IN PART and DENIED IN PART.

Defendants' motion to dismiss is granted with respect to Lead Plaintiffs' Section 10(b) and 20(a) claims to the extent they are based on Defendants' statements describing Rexista's abuse-deterrent features and its bioequivalence to OxyContin. Defendants' motion to dismiss is

denied with respect to Lead Plaintiffs' Section 10(b) and 20(a) claims based on Defendants' statements describing the contents of the Rexista NDA as filed with the FDA.

Defendants shall file answers to the remaining claims within 21 days of the date of this Order. The Clerk of Court is directed to close the motion at Docket Number 29.

SO ORDERED.

Dated: December 17, 2018
New York, New York

J. PAUL OETKEN
United States District Judge