UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IMMANUEL LAKE, et al.,

Plaintiffs,

v.

ZOGENIX, INC., et al.,

Defendants.

Case No. 19-cv-01975-RS

ORDER GRANTING IN PART AND DENYING IN PART REQUESTS FOR INCORPORATION BY REFERENCE AND DISMISSING COMPLAINT WITH LEAVE TO AMEND

I. INTRODUCTION

Plaintiffs Immanuel Lake and Arnold Keijzer bring this putative class action for securities fraud against Zogenix, Inc., a U.S.-based pharmaceutical company, and two members of Zogenix leadership, co-founder and CEO Stephen Farr, and Chief Financial Officer Michael Smith. Plaintiffs allege that Zogenix withheld material information from the public when discussing the New Drug Application ("NDA") it was submitting to the U.S. Food and Drug Administration ("FDA") for FINTEPLA, a medication designed to treat seizures. Plaintiffs further claim that this omission caused plaintiffs to purchase Zogenix stock at inflated prices and then caused plaintiffs a corresponding economic loss when the alleged omission was revealed to the market through the FDA's rejection of the FINTEPLA NDA. Defendants move to dismiss, claiming plaintiffs' First Amended Complaint ("FAC") fails to plead falsity and scienter with particularity as required under the Private Securities Litigation Reform Act ("PSLRA"). *See* 15 U.S.C. § 78u-4(b). In support of their motion to dismiss and reply briefing, defendants request this Court incorporate by

reference or, alternatively, take judicial notice of, 15 exhibits. *See* Dkts. 47-2; 54-2. These requests are granted-in-part and denied-in-part as explained below. On the motion to dismiss, because the FAC's allegations of falsity and scienter fail to satisfy the PSLRA's heightened pleading standard, defendants' motion to dismiss is granted, and the FAC is dismissed with leave to amend.

II. BACKGROUND[1]

Zogenix is a biotechnology company headquartered in Emeryville, California that specializes in developing therapies for people suffering from severe conditions affecting the central nervous system. This litigation concerns Zogenix's most promising product candidate, a drug called FINTEPLA, designed to treat two debilitating forms of childhood-onset epilepsy, Dravet syndrome and Lennox-Gastaut syndrome.[2]

Although Zogenix is still in the midst of the arduous process of gaining FDA approval for this potential blockbuster drug, the active ingredient in FINTEPLA is fenfluramine, a chemical compound which was previously approved by the FDA at a higher dose in 1973 to treat adult obesity.[3] Based on the FDA's prior approval of fenfluramine, the FDA informed Zogenix that the company would be able to submit its NDA for FINTEPLA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which provides for a more streamlined pathway for FDA approval. Specifically, Section 505(b)(2) permits an applicant to rely partly on investigations conducted by other parties or publicly available literature in lieu of duplicating costly and time-intensive studies.

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[1] The factual background is based on the averments in the FAC (which must be taken as true for purposes of this motion), documents incorporated by reference, and documents of which the Court may take judicial notice. *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003); *see generally* Part III, *infra*.

[2] The parties also refer to FINTEPLA by another name, ZX008. For consistency, this order uses FINTEPLA throughout.

[3] This FDA-approved weight loss drug containing fenfluramine was called Pondimin. It was taken off the market years after it received FDA approval once reports surfaced that, when taken in conjunction with another drug, phentermine, (thereby creating a combination referred to as "fen-phen"), it could lead to increased risk of valvular heart disease.

When Zogenix informed investors that, based on its conversations with the FDA, this 505(b)(2) pathway would be available for FINTEPLA, the market reacted favorably to the news.

In 2016, Zogenix began clinical trials of FINTEPLA.[4] The results of the first trial, announced in September 2017, showed the drug reduced the frequency of convulsive seizures in patients with Dravet Syndrome. The results of the second trial, announced in July 2018, were consistent and suggested FINTEPLA was superior to existing treatments for Dravet Syndrome. Moreover, neither trial suggested FINTEPLA was associated with an increased risk of valvular heart disease, the complication associated with the fenfluramine-phentermine combination which led to Pondimin being taken off the market.

On February 6, 2019, Zogenix announced in a press release that it had "completed its rolling submission" of its NDA for FINTEPLA to the FDA (and completed an equivalent submission to the European Medicines Agency). However, just two months later on April 8, 2019, Zogenix announced that it had received a Refusal-to-File ("RTF") letter from the FDA, signifying that the FDA found the NDA did not satisfy the threshold requirements to warrant a complete, substantive review. On a conference call with analysts following the announcement of this disappointing rejection, Zogenix shared that the FDA cited two reasons for its decision: (1) "certain nonclinical studies were not submitted to assess toxicity"; and (2) "the application contained an incorrect version of a clinical study dataset." After the news of the RTF letter hit the market, Zongenix stock fell approximately 20 per cent, and the company experienced a one-day market capitalization loss of nearly $500 million.

Plaintiffs allege the FINTEPLA NDA was essentially doomed from the start, because Zogenix opted not to include references to existing non-clinical fenfluramine toxicity literature, preferring instead to rely solely on the strength of its own recent clinical trials. Plaintiffs argue that, because Zogenix had touted the benefits of being able to submit the FINTEPLA NDA through the 505(b)(2) pathway—a cheaper, expedited pathway that leverages prior studies and

[4] Regulatory approval for a new drug requires both non-clinical studies (conducted in animals to assess pharmacology and toxicity) and clinical trials (conducted in humans).

published literature references and data previously reviewed by the FDA—the market was led to believe the prior non-clinical toxicology studies on fenfluramine would be included in the NDA. Therefore, plaintiffs contend that Zogenix's announcement that it had completed its NDA filing without also disclosing that it opted *not* to reference these prior toxicity studies, was a material omission that concealed from the market the "exceedingly high risk that the FDA would refuse to file the NDA due to the absence of necessary toxicology studies." FAC, Dkt. 42 at ¶ 55. Plaintiffs characterize the statements of defendant Farr, made after Zogenix received the RTF letter, that "[w]e know that there are literature data on chronic toxicology with fenfluramine based upon the prior NDA for [Pondimin]" and that they "*were going to* reference the chronic toxicity from the old Pondimin days, reference it through literature . . . " as admissions that Zogenix intentionally excluded the prior literature from the NDA, despite it allegedly being a requirement for approval under Section 505(b)(2). Opp. to Mot. to Dismiss ("Opp."), Dkt. 52 at 14. Plaintiffs also point to statements surrounding Zogenix's later resubmission of the FINTEPLA NDA, noting this revised NDA was supplemented with "additional clinical and non-clinical literature," as further evidence that this non-clinical toxicity literature was conspicuously absent from the original NDA. *Id.* at 14 n.3.

Plaintiffs filed this putative class action in April 2019 against Zogenix, Stephen Farr, and Michael Smith, bringing claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Defendants moved to dismiss in October 2019, and a hearing was held in January 2020. In support of their motion to dismiss and their reply brief, defendants moved for incorporation by reference or judicial notice of certain documents. This ancillary request is addressed first.

III. REQUESTS FOR INCORPORATION BY REFERENCE

A. 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. *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). However, "[t]here are two exceptions to

this rule: the incorporation-by-reference doctrine, and judicial notice under Federal Rule of Evidence 201." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (noting documents incorporated by reference and "matters of which a court may take judicial notice" are properly considered when ruling on a motion to dismiss).

"Incorporation-by-reference is a judicially created doctrine that treats certain documents as though they are part of the complaint itself." *Khoja*, 899 F.3d at 1002. A defendant may seek to incorporate a document into the complaint "if the plaintiff refers *extensively* to the document or the document forms the basis of the plaintiff's claim." *Ritchie*, 342 F.3d at 907 (emphasis added). "The doctrine prevents plaintiffs from selecting only portions of documents that support their claims, while omitting portions of those very documents that weaken—or doom—their claims." *Khoja*, 899 F.3d at 1002. In general, "a court may assume an incorporated document's contents are true for purposes of a motion to dismiss under Rule 12(b)(6) . . . [but] 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." *Id.* at 1003 (internal quotations and citations omitted).

"Judicial notice under Rule 201 permits a court to notice an adjudicative fact if it is 'not subject to reasonable dispute.'" *Id.* at 999 (citing Fed. R. Evid. 201(b)). "A fact is 'not subject to reasonable dispute' if it is 'generally known,' or 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.' *Id.* (citing Fed. R. Evid. 201(b)(1)–(2)). "Accordingly, a court may take judicial notice of matters of public record without converting a motion to dismiss into a motion for summary judgment . . . [b]ut a court cannot take judicial notice of disputed facts contained in such public records." *Id.* (quotation marks and citation omitted).

B. Discussion

In support of their motion to dismiss, defendants seek incorporation by reference and/or judicial notice of the following 13 documents, termed "exhibits" for ease of reference:

(1) a press release dated February 6, 2019, entitled "Zogenix Submits New Drug Application

to U.S. Food & Drug Administration and Marketing Authorization Application to European Medicines Agency for FINTEPLA® for the Treatment of Dravet Syndrome";

(2) Zogenix, Inc.'s 2018 Form 10-K, dated February 28, 2019;

(3) Zogenix, Inc's FQ4 2018 Earnings Call Transcript, dated February 28, 2019;

(4) a press release dated April 8, 2019, entitled "Zogenix Receives Refusal to File Letter from U.S. Food and Drug Administration for FINTEPLA® New Drug Application";

(5) a Zogenix, Inc. "Special Call Transcript," dated April 8, 2019;

(6) Zogenix, Inc.'s FQ1 2019 Earnings Call Transcript, dated August 10, 2015;

(7) a press release, dated June 27, 2019, entitled "Zogenix Announces FDA Agreement to Proceed with Resubmission of FINTEPLA® NDA";

(8) Zogenix, Inc.'s FQ2 2015 Earnings Call Transcipt, dated August 10, 2015;

(9) the historical ZGNX Stock Price Chart from Yahoo Finance from February 1, 2019 through June 28, 2019;

(10) a report from Ladenburg Thalmann Financial Services from April 9, 2019, entitled "Zogenix, Inc. – Fintepla Stumbles with FDA; Approval Remains Likely; Buy, PT Lowered to $50";

(11) a report from Guggenheim Securities from April 9, 2019, entitled "ZGNX – Downgrading to Neutral – Many Questions but Limited Visibility; Worst Case Could Be >1.5 Year Setback";

(12) a report from Northland Securities from April 9, 2019, entitled "Zogenix, Inc. (ZGNX) – RTF Letter – An Unexpected Speed Bump"; and

(13) a publicly-available FDA guidance document dated May 2009, entitled "Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants"

Dkt. 47-2 at 1. In addition, defendants request the same for two additional exhibits filed in support of their reply brief:

(14) a call transcript, entitled "Company Conference Presentation" dated May 15, 2019;

(15) a Guggenheim Securities Report, entitled "ZGNX – 1Q19; Type A Meeting Scheduled

> for June; NDA Resubmission Update Likely in the June/July Timeframe" dated May 9, 2019."

Dkt. 54-2 at 1. Plaintiffs do not oppose defendants motions in their own filing.

The Ninth Circuit in *Khoja* recently criticized a "concerning pattern in securities cases" in which defendants "exploit[] [judicial notice and incorporation-by-reference procedures] improperly to defeat what would otherwise constitute adequately stated claims at the pleading stage." 899 F.3d at 998. Given the already heightened pleading standards for securities fraud cases, "if defendants are permitted to present their own version of the facts at the pleading stage [through improperly incorporated or noticed documents]—and district courts accept those facts as uncontroverted and true—it becomes near impossible for even the most aggrieved plaintiff to demonstrate a sufficiently 'plausible' claim for relief. *Id.* at 999 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). With this admonition in mind, the specific exhibits at issue are addressed as follows.

Exhibits 1 through 5 may be incorporated by reference because plaintiffs allege that each of these sources either contained a false or misleading statement or served as a corrective disclosure. *See, e.g.*, FAC ¶¶ 30, 36, 47, 57, 65. Moreover, although exhibits 4 and 5 are referenced only once each in the FAC, they "form the basis of [plaintiffs'] claims" and are therefore properly incorporated by reference. *Khoja*, 899 F.3d at 1006. Similarly, exhibits 6 through 8 may be incorporated by reference because each forms the basis of plaintiffs' scienter or falsity allegations. *See, e.g.*, FAC ¶¶ 66 (quoting exhibit 6 at length to support scienter); 43 (quoting exhibit 7 and suggesting the reference to "additional clinical and non-clinical literature" included in the NDA resubmission bolsters the FAC's falsity allegations); 61 (quoting exhibit 8, also referenced elsewhere, to support scienter).

The Court may take judicial notice of exhibit 9, the chart showing the historical stock price and trading volume for Zogenix stock during the class period and beyond, from February 1, 2019 through June 28, 2019. *See In re Facebook, Inc. Sec. Litig.*, 405 F. Supp. 3d 809, 828 (N.D. Cal. 2019) ("Information about the stock price of publicly traded companies is the proper subject of

judicial notice") (internal quotation and brackets omitted). This information falls squarely within Rule 201.

Exhibits 10 through 12 may not be incorporated by reference. None of these analyst reports is quoted "extensively" in the complaint, nor do these reports "form the basis of [plaintiff's] claims." *Khoja*, 899 F.3d at 1003. Defendants disagree, arguing they are critical to plaintiff's claims "to establish what was in the public realm at the relevant time." Request for Incorporation by Reference & Judicial Notice in Support of Mot. to Dismiss, Dkt. 47-2 at 6. This is an insufficient justification for appending to plaintiff's FAC 31 pages of financial analysis. These exhibits are referenced in passing only twice (only once in the case of Exhibit 11) to convey plaintiff's interpretation of analyst sentiments. To set so low a bar for "forming the basis of [plaintiff's] claims" would reduce *Khoja*'s admonition to empty words. Taking judicial notice of these three exhibits, requested by defendants in the alternative to show "what may or may not have been disclosed to the public," is likewise inappropriate. *Id.* at 7. It is not clear the precise facts defendants want judicially noticed from these documents, and this confusion merely reinforces why this doctrine is inappropriate in this instance. *See* Fed. R. Evid. 410 (permitting judicial notice of adjudicative *facts*, not documents).

Exhibit 13, a publicly available FDA guidance document, is also properly subject to judicial notice. "[C]ourts routinely take judicial notice of [] FDA guidance documents, many of which also appear on the FDA's public website." *Allen v. ConAgra Foods, Inc.*, 2018 WL 6460451, at *8 n.6 (N.D. Cal. Dec. 10, 2018) (internal quotation omitted). Because this document is currently accessible on the FDA's website (specifically, at *https://www.fda.gov/media/72253/download*) as of the date of this order, its "accuracy cannot reasonably be questioned," making it subject to judicial notice. Fed. R. Evid. 201(b).

Exhibit 14 may be incorporated by reference because this transcript is quoted at length in the FAC to support the inference of scienter and plaintiffs' theory of defendants' "gamble." FAC ¶ 68; *see also Khoja*, 899 F.3d at 1004 (affirming district court's incorporation of a blog post quoted once, but in a lengthy quotation conveying numerous facts); *Ritchie* 342 F.3d at 907

(approving of incorporation by reference for documents referenced "extensively" by plaintiffs).

Defendants overreach, however, in seeking judicial notice of exhibit 15. This report from Guggenheim Securities dated May 15, 2019 is not cited or referenced in the FAC. Defendants argue exhibit 15 is nonetheless ripe for judicial notice because an *earlier* analyst report from the same firm (*i.e.* exhibit 11, from the prior month) was selectively quoted by plaintiffs. Defendants are careful to clarify that they seek judicial notice of this report "'not in order to take notice of the truth of the matters asserted therein, but in order to determine what may or may not have been disclosed to the public.'" Dkt. 54-2 at 4 (quoting *In re Regulus Therapeutics Inc. Sec. Litig.*, 2019 WL 4242485, at *5 (S.D. Cal. Sept. 5, 2019). To take judicial notice of this later analyst report, however, would constitute the very sort of excessive use of extrinsic material against which the Ninth Circuit recently cautioned in *Khoja*. Given the rulings above on the first 14 exhibits, to take judicial notice of exhibit 15, even for this limited purpose, would risk unduly prejudicing plaintiffs at this early stage, "where there is already a heightened pleading standard, and the defendants possess materials to which the plaintiffs do not yet have access." *Khoja*, 899 F.3d at 998.

Accordingly, defendants' first motion for incorporation by reference and judicial notice (Dkt. 47-2), applicable to exhibits 1 through 13, is granted with respect to exhibits 1 through 9 and exhibit 13, but denied with respect to exhibits 10 through 12, as explained above. Defendants' second such motion (Dkt. 54-2), applicable to exhibits 14 and 15, is granted with respect to exhibit 14 but denied with respect to exhibit 15.

IV. MOTION TO DISMISS

A. Legal Standard

A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). While "detailed factual allegations are not required," a complaint must include sufficient facts to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible "when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Claims grounded

in fraud are also subject to Rule 9(b), which provides that "[i]n allegations of fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To satisfy that rule, a plaintiff must allege the "who, what, where, when, and how" of the charged misconduct. *Cooper v. Pickett*,137 F.3d 616, 627 (9th Cir.1997).

A motion to dismiss a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure tests the legal sufficiency of the claims alleged in the complaint. *See Parks Sch. of Bus. v. Symington*, 51 F.3d 1480, 1484 (9th Cir.1995). Dismissal under Rule 12(b)(6) may be based either on the "lack of a cognizable legal theory" or on "the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir.1988). When evaluating such a motion, the court must accept all material allegations in the complaint as true, even if doubtful, and construe them in the light most favorable to the non-moving party. *Twombly*, 550 U.S. at 570. "[C]onclusory allegations of law and unwarranted inferences," however, "are insufficient to defeat a motion to dismiss for failure to state a claim." *Epstein v. Wash. Energy Co.*, 83 F.3d 1136, 1140 (9th Cir.1996); *see also Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555 ("threadbare recitals of the elements of the cause of action, supported by mere conclusory statements," are not taken as true)). In actions governed by the PSLRA, such as this one, these general standards are subject to further refinement, as discussed in more detail below.

B. Discussion

1. Count I – Section 10(b) of the Exchange Act

Section 10(b) of the Exchange Act makes it unlawful for "any person ... [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Pursuant to Section 10(b), the Securities and Exchange Commission has promulgated Rule 10b–5, which provides, *inter alia*, that "[i]t shall be unlawful for any person . . . [t]o engage in any act, practice,

or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b–5(c).

To establish a violation of Rule 10b–5, a plaintiff must demonstrate "(1) a material misrepresentation or omission of fact [*i.e.* falsity], (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." *In re Daou Systems, Inc. Sec. Litig.*, 411 F.3d 1006, 1014 (9th Cir. 2005). To survive a motion to dismiss, a complaint asserting claims under section 10(b) and Rule 10b–5 must satisfy the dual pleading requirements of Rule 9(b) and the PSLRA. *Zucco Partners v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir.2009).

i. *Falsity*

Under the PSLRA, to allege falsity a complaint must, "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, . . . state with particularity all facts on which that belief is formed." *Gompper v. VISX, Inc.*, 298 F.3d 893, 895 (9th Cir.2002) (quoting 15 U.S.C. § 78u–4(b)(1)) (quotation marks omitted). A statement is misleading "if it would give a reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exists.'" *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008) (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)). Further, an omitted fact is material "when there is a substantial likelihood that [its disclosure] would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (internal citations omitted).

Plaintiffs allege eight materially misleading omissions, which can be classified into four general categories: (1) statements concerning Zogenix's completion of its rolling submission of the NDA; (2) statements that the NDA was "based on data from two pivotal Phase 3 trials in Dravet syndrome"; (3) statements describing Zogenix's potential use of the Section 505(b)(2) regulatory pathway; and (4) statements concerning the potential for the FDA to require additional

studies.

As noted above, plaintiffs' FAC attempts to plead falsity under an omissions theory, as they must, given all eight alleged misstatements are factually true. That is, Zogenix *did* complete its "rolling submission of an NDA to the U.S. Food and Drug Administration" as announced in its February press releases, the NDA *was* primarily "based on data from two pivotal Phase 3 trials in Dravet syndrome and an interim analysis from an ongoing open-label extension study," *et cetera.* Plaintiffs rightfully emphasize, however, that "[s]ome statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is not measured by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers." *Miller v. Thane Int'l, Inc.*, 519 F.3d 879, 886 (9th Cir. 2008) (internal quotation omitted). Plaintiffs argue the statements about Zogenix completing its NDA submission, while literally true, failed to disclose to investors that Zogenix chose *not* to refer to publicly available literature on non-clinical fenfluramine studies as part of its NDA, which caused a "significantly heighted risk" of a rejection by the FDA. Opp. at 11.

A first step in the falsity analysis requires a close examination of what exactly plaintiffs accuse Zogenix of concealing from the market. In this case, however, the inquiry must start with the preliminary issue of what exactly plaintiffs claim was omitted from the NDA, which in turn allegedly should have been disclosed to the market. On this fundamental point, plaintiffs are imprecise.[5] Both the FAC and plaintiffs' opposition brief at times suggest that Zogenix's NDA

[5] Admittedly, plaintiffs are at a disadvantage when trying to plead precisely what the NDA did or did not contain, because they have not even seen the application, which is non-public and confidential. 21 C.F.R. §§ 601.50-51. Zogenix has also not disclosed a copy of the RTF letter to the public, so plaintiffs similarly lack the benefit of being able to read the FDA's rationale behind the RTF letter in the FDA's own words. Opp. at 7. Plaintiffs are left to speculate as to the contents of both the NDA and RTF letter based on Zogenix's statements to the investors, analysts, and the public, absent the use of confidential witnesses. The fact that the NDA is confidential and the RTF letter has not been made public, however, does not relieve Plaintiffs of their obligation to meet the exacting pleading standards of the PSLRA. *See Bauer v. Eagle Pharm., Inc.*, No: 16-cv-03091, 2017 WL 2213147, at *7 (D.N.J. May 19, 2017) ("While the Court acknowledges that Plaintiffs may lack information due to the confidentiality of the [FDA's critical response letter], this fact does not give Plaintiffs the authority to speculate. That is, speculation and conjecture will

did not include *any* reference whatsoever to prior literature or research on fenfluramine. *See, e.g.*, FAC at ¶ 2 ("[W]hen push came to shove[,] Zogenix never incorporated the publicly available data for fenfluramine in its NDA . . . ."); *id.* at ¶ 8 ("Defendants subjected investors to a material and undisclosed risk by omitting the public fenfluramine literature from Zogenix's NDA."); Opp. at 14 n.4 ("Defendants cannot credibly argue that they were unaware of the public literature requirement (even putting aside the plain language of Section 505(b)(2) which explicitly requires it)"). Elsewhere, however, the FAC and Opposition brief clarify that, according to plaintiffs, the critical pieces left out of the NDA (without being disclosed to the market) were references to existing fenfluramine *toxicity* literature, specifically "the six- and nine-month toxicity studies under ICH." Opp. at 14; *see also* FAC at ¶ 37 ("The particular studies Zogenix omitted were standard 6- and 9-month chronic toxicity studies under the International Conference on Harmonisation ['ICH'] (an entity that coordinates pharmaceutical regulations across different countries).").

This distinction is significant to the falsity analysis. As plaintiffs argue, the Section 505(b)(2) pathway is generally reserved for products that incorporate already-approved pharmacological agents. Therefore, omitting in the NDA *any reference* to fenfluramine's prior use in an FDA-approved drug while publicly touting the likely availability of the 505(b)(2) pathway could constitute a material omission, the disclosure of which could plausibly "significantly alter[] the 'total mix' of information" relevant to a reasonable investor. *Matrixx Initiatives, Inc.*, 563 U.S. at 38. Read carefully, however, Plaintiffs' complaint does not appear to be making this broader allegation, given the repeated references to 6- and 9-month toxicity studies specifically. If, however, plaintiffs were in fact alleging that the NDA did not contain a single reference to prior studies or publicly available literature on fenfluramine, they did not do so with the requisite particularity in the FAC.[6]

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not support a claim under the PSLRA's heightened pleading standard.").

[6] Because plaintiffs have been granted leave to amend, they have an opportunity to plead unambiguously that the NDA did not contain a single reference to prior research on fenfluramine.

Moving then to the more precise alleged omission—*i.e.* that Zogenix failed to inform the market that the NDA did not reference "standard 6- and 9-month chronic toxicity studies under the [ICH]"—this too falls short of constituting a material omission for the purpose of adequately pleading falsity.[7] Rather, this is the very sort of fraud-by-hindsight reasoning that the PSLRA was enacted to avoid. *See In re Intrabiotics Pharm., Inc. Sec. Litig.*, No. 04-cv-02675, 2006 WL 708594, at *8 ("The heightened standard set by the PSLRA was intended to put an end to securities fraud lawsuits that plead 'fraud by hindsight') (quoting *In re Silicon Graphics, Inc. Sec. Lit.*, 183 F.3d 970, 988 (9th Cir. 1999)); *see also Reese v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 693 (9th Cir. 2011) (expressing the "general principle" that "to be actionable, a statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events") (internal quotations omitted). Plaintiffs appear to assume that defendants knew, at the time of filing the NDA, that the failure to reference the 6- and 9-month toxicity studies made the application facially deficient and created an "exceedingly high risk" of rejection, but plaintiffs pleaded no specific allegations to support this critical assumption. *See In*

Although such allegations, if pleaded with sufficient particularity, would be taken as true at the motion to dismiss stage, it is worth noting that defendants categorically deny this broader claim. *See* Reply Br. in Support of Mot. to Dismiss ("Reply"), Dkt. 54 at 3 ("Zogenix submitted a robust non-clinical package, *with references to previous use of fenfluramine* and new non-clinical studies . . . .") (emphasis added); *id.* at 11-12.

[7] As defendants point out, plaintiffs also did not make a particularly strong showing that references to nonclinical toxicology studies of this sort were actually excluded from the NDA. Defendant Farr's statement that they "were going to reference the chronic toxicity . . . literature" was not necessarily an admission that they did not end up doing so. *See* Opp. at 6-7. Indeed, Dr. Farr concluded his statement by noting "all that was basically laid out in our regulatory documentation." Dkt. 54-1, Ex. 14 at 24. Moreover, Zogenix's public statements on the RTF letter it received from the FDA could be interpreted to suggest the FDA wanted Zogenix to *conduct* these six- and nine-month toxicity studies, rather than add references to publicly available prior literature on such studies. *See, e.g.*, Dkt. 47-1, Ex. 5 at 9 ("If the studies are required then obviously we'll need to conduct them . . . ."). It is not entirely clear, therefore, that the premise underlying plaintiffs' entire case (*i.e.* that reference to prior 6- and 9-month toxicity studies were omitted from the NDA) is even accurate. For purposes of a motion to dismiss, however, plaintiffs' allegation that references to these specific studies were lacking must be taken as true. *Twombly*, 550 U.S. at 570; *see also Khoja*, 899 F.3dat 1003 ("[I]t is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint.").

re PTC Therapeutics, Inc. Sec. Litig., No. 16-cv-1124, 2017 WL 3705801, *11 (D.N.J. Aug. 28, 2017) (granting dismissal as to certain statements because plaintiffs "simply assumed" defendants knew it could not meet certain FDA requirements without ever "specify[ing] the contents of those requirements, or stat[ing] who knew about them and when"). "More is required to bridge the gap between conceivability and plausibility." *Id.*

Indeed, were plaintiffs' version of falsity the law, a pharmaceutical company could be sued for securities fraud each and every time it received a NDA rejection from the FDA. Potential plaintiffs could merely parrot any deficiency identified by the FDA rejection letter and then claim the company concealed from the market that it failed to include this "necessary" piece of information in its application. Plaintiffs would further claim that the company knowingly concealed from the market the corresponding "exceedingly high risk" of FDA rejection. These same potential plaintiffs would then classify the company's decision to omit whatever, *in hindsight*, the FDA said was missing from the NDA as a "reckless gamble," and the inevitable decline in the stock price would be classified as a monetary loss *caused* by this material omission.

More is required to plead securities fraud under Section 10(b) and Rule 10b-5, as the case law has made clear. First, there is no general obligation to disclose to the public every strategic decision made in a NDA. *See In re Dynavax Sec. Litig.*, 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018); *see also In re Rigel Pharm, Inc. Sec. Litig.*, 697 F.3d 869, 880 n.8 (9th Cir. 2012). This makes sense, given Rule 10b-5 contains no "freestanding completeness requirement." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). Rather, "[t]o be actionable under the securities laws, an omission must be misleading; in other words it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Id.* (citation omitted). Therefore, Zogenix would have had a duty to disclose its decision to exclude these 6- and 9-month studies only if its failure to disclose as much would create a materially misleading impression of the progress of FINTEPLA's FDA approval. This is not the case. Rather, none of Plaintiffs' eight alleged misstatements meets this high bar for a materially misleading omission, primarily because none pretends to discuss what precise prior studies and

research on fenfluramine would or would not be included in the NDA.

The cases plaintiffs cite in support of its omission theory are illustrative and bolster the argument for dismissal. In each of these cases, the plaintiffs were found to have pleaded falsity with particularity under an omissions theory precisely because defendants in those cases were already in possession of information that directly contradicted their public statements when made. *See Khoja*, 899 F.3d at 1008 ("Falsity is alleged when a plaintiff points to defendant's statements that directly contradict what the defendant knew at that time.").

In *Khoja*, for example, defendants were touting positive interim results of a study without also disclosing that the FDA had already explicitly warned defendants that these same results had "a high degree of uncertainty" and were therefore unreliable. *Id.* at 1010. Contrast this with the alleged omissions here, where plaintiffs have brought forth no facts to show defendants knew the NDA was destined for rejection in light of their alleged failure to reference 6- and 9-month toxicology studies.

Similarly, in *Matrixx Initiatives Inc. v. Siracusano*, 563 U.S. 27, 45-47 (2012), plaintiffs adequately pleaded that defendants had made misleading statements that concealed a significant risk to the viability of the company's leading product. Matrixx had received multiple reports from three medical professionals and researchers linking its leading product to a serious medical condition in patients. Instead of disclosing the risk that these reports about its leading product (which accounted for nearly 70% of the company's total sales) were true, Matrixx dismissed the reports as "completely unfounded and misleading." *Id.* at 47. "Importantly, however, Matrixx had evidence of a biological link between [the product's] key ingredient and [the adverse health condition], and it had not conducted any studies of its own to disprove that link." *Id.* Unlike in *Matrixx*, Zogenix is not alleged to have received reports or guidance from the FDA that its NDA was doomed to fail if it excluded reference to these particular 6- and 9-month studies. Rather, plaintiffs simply assume as much with the benefit of hindsight.

Likewise, in *In re Amylin Pharm., Inc. Sec. Litig.*, 2003 WL 21500525, *5 (S.D. Cal. May 1, 2003), the court found plaintiffs had adequately pleaded falsity by alleging that defendants

publicly advertised the FDA's approval of its phase III trials methodology while omitting that the FDA had in fact highlighted particular ways in which its methodology was "inconsistent with clinical practice" and would therefore be difficult for the FDA to evaluate. *In re Amylin Pharm., Inc. Sec. Litig.*, No. 01-cv-1455, 2002 WL 31520051, at *4 (S.D. Cal. Oct. 10, 2002), amended on other grounds in *In re Amylin Pharm., Inc. Sec. Litig.*, 2003 WL 21500525. The court also found plaintiff adequately pleaded a material omission where defendants publicly celebrated successful phase III test results with "no increase in severe hypoglycemic events," when in fact the company itself acknowledged severe hypoglycemia as a "side effect issue[] of concern" at a meeting with an FDA Advisory Panel because rates of severe hypoglycemia "increased during the first four weeks of therapy." *Id.* at *6. Amylin therefore had in its possession *specific information*—in the one case, statements by the FDA calling its Phase III methodology into question, and in the other case, evidence of an increased prevalence of a harmful side effect—which, because it was not disclosed, made the company's public statements on the subjects materially misleading.

Here, by contrast, plaintiffs' FAC does not point to similarly concrete information in Zogenix's possession that contradicted its public statements surrounding the filing of the NDA. Rather, armed with 20/20 hindsight, plaintiffs simply impute onto defendants knowledge of an "exceedingly high risk" that, without reference to the particular, "necessary" studies in question, the FDA would refuse to file the NDA. *See, e.g.*, FAC ¶ ¶ 46, 55. Plaintiffs point to no specific comments from the FDA warning plaintiffs of this risk, nor is the need to reference particular 6- and 9-month toxicology studies self-evident from the open-ended language of Section 505(b)(2), notwithstanding Plaintiff's allegations to the contrary. *Compare* 21 U.S.C. § 355(b)(2) *with* FAC ¶ 37.

Defendants' alleged decision to exclude reference to prior 6- and 9-month toxicity studies on fenfluramine simply does not render any of the categories of challenged statements misleading. They remain true statements which do not require clarification. Indeed, Zogenix *had* completed its rolling NDA submission; Zogenix's NDA *did* rely on data from two clinical trials; if made available by the FDA, the 505(b)(2) pathway "*would* allow [the NDA] to rely in part on data in the

public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds . . . ."; and the FDA *may* condition NDA approval on Zogenix's agreement to conduct additional studies. These challenged statements are different in kind from the statements found to be materially misleading in the case law surveyed above.

Admittedly, the third category of challenged statements on the availability of the 505(b)(2) pathway comes the closest to implying that reference to prior studies would not be omitted, but it still falls short of being materially misleading. *See* FAC ¶ 54. This is because, as noted above, Section 505(b)(2) says nothing about what specific references or studies a NDA must include. The statute merely permits an applicant to rely on "investigations . . . [that] were not conducted by or for the applicant," and the accompanying regulations clarify that the precise studies required are case-specific and depend on the nature of the drug. 21 U.S.C. § 355(b)(2); *see also* 21 C.F.R. §§ 312.22(b), 314.50. Therefore, a reasonable investor would not have assumed that Zogenix's NDA would reference each and every prior study and all publicly available literature on fenfluramine. A reasonable investor would rather have assumed that Zogenix would make its best efforts to reference those prior studies and research that it thought necessary to gain approval. That Zogenix may have ultimately been wrong in its assessment of what prior literature on fenfluramine the FDA wanted to see does not make the company's prior statements about its NDA fraudulent. Zogenix was permitted to allude to the possibility of using the Section 505(b)(2) pathway without having to disclose which prior studies it did and did not specifically incorporate in its NDA.

In sum, the FAC fails to plead that Zogenix's failure to disclose its purported decision to exclude reference to prior 6- and 9-month chronic toxicity studies in its NDA was a material omission within the meaning of the securities laws. The complaint therefore fails to plead falsity with the requisite particularity and must be dismissed on that ground.

ii. *Scienter*[8]

[8] While the FAC's failure to plead falsity with particularity mandates dismissal, because plaintiffs are granted leave to amend, this order also addresses defendants' challenges to plaintiffs' allegations of scienter to alert plaintiffs of the FAC's deficiencies in pleading this separate

Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007) (internal quotation marks omitted). To plead scienter adequately under the PSLRA, the complaint 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); *see also Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). To qualify as a "strong inference," the Supreme Court has held, "an inference of scienter must be more than merely plausible or reasonable." *Tellabs*, 551 U.S. at 314. When determining whether there are sufficient allegations of scienter, courts "must consider the complaint in its entirety . . . [and inquire] 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." *Id.* at 322–23. Moreover, courts must take into account plausible opposing inferences. *Id.* at 323. A complaint will survive a motion to dismiss "only if 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.* at 324.

Plaintiffs attempt to plead scienter by characterizing defendants' decision to file the NDA without reference to the prior 6- and 9-month toxicity studies as a "deliberate and reckless gamble." Opp. at 19; *see also* FAC ¶¶ 2, 68-69. Plaintiffs aver that, although defendants were well aware of the prior fenfluramine studies and aware that by excluding them from the NDA, they "exponentially increased the likelihood that the FDA would reject the FINTEPLA NDA," defendants nevertheless opted to exclude the required references anyway and run the risk of rejection, all without informing the market of their risky wager. Opp. at 20.

Plaintiffs' narrative does not create a plausible inference of scienter sufficient to escape dismissal. As noted above, there are no particular allegations in the FAC that the FDA informed Zogenix these *particular* studies were required, nor are there specific allegations that defendants intentionally flouted any such guidance. Moreover, Plaintiffs have no answer to defendants'

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element.

benign explanation—namely that "Zogenix had every incentive to get it right the first time, and to put FINTEPLA on the path to approval," did not consciously engage in any "reckless gamble," but rather misread what the FDA was looking for in the FINTEPLA NDA. MTD at 23. Indeed, of the approximately $500 million that disappeared from Zogenix's market capitalization over the 24 hours following the announcement of the RTF letter, presumably a meaningful portion of that belonged to named defendants Farr and Smith. This is not a case where plaintiffs support their inference of scienter with claims of insider stock sales, performance incentives, or the need to close a round of fundraising at an inflated valuation. *See, e.g.*, *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 813 (C.D. Cal. 2011). In fact, plaintiffs appear to concede in their opposition brief that they have not uncovered a plausible motive, but instead argue this is "beside the point." *See* Opp. at 24 ("Whether Zogenix excluded the fenfluramine references . . . to avoid potential negative associations with Fen-Phen . . . a desire to cut corners, proceed solely with their own studies rather than associate with prior studies, or any other reason, is beside the point."). Unfortunately for plaintiffs, it is anything but. While "motive" is not, itself, an element of securities fraud and although the absence of a motive is not dispositive, the existence of a plausible motive *is* directly relevant to the scienter analysis. *Matrixx Initiatives, Inc.*, 563 U.S. at 48. It is a court's task to determine whether the inference of scienter is "at least as compelling as any opposing inference," and a motive—or lack thereof—goes directly to the strength of that inference. *Tellabs*, 551 U.S. at 324. Indeed, "the strength of an inference cannot be decided in a vacuum. The inquiry is inherently comparative." *Id.* at 323.

The hypothetical rationales proposed by plaintiffs for why defendants would jeopardize FDA approval for FINTEPLA by excluding required, easily accessible information while also intentionally concealing this decision from the market simply do not hold water. Avoiding negative associations with the "fen-phen" combination would be no reason to jeopardize approval for a potential blockbuster drug, particularly since the health risks associated with "fen-phen" have apparently not surfaced in any FINTEPLA studies or trials thus far, and because the FDA had already openly discussed fenfluramine's prior approval with defendants. Nor is "cutting corners"

a plausible justification for taking on this allegedly "exceedingly high risk" of rejection, particularly after Zogenix had been pursuing FDA approval for years at an exorbitant cost. Far more plausible is the non-fraudulent inference offered by defendants, namely that Zogenix submitted an NDA it believed was consistent with prior FDA guidance and was likely to be approved. *See* FAC ¶ 65 (quoting defendant Farr's statement on an investor call that "[w]e have conducted what we believe, based upon our FDA correspondence, was the appropriate nonclinical package for the NDA . . . .").

A case relied on by plaintiffs again provides a helpful contrast. In *Matrixx*, summarized above, the Supreme Court also affirmed the Ninth Circuit's finding that the plaintiffs had adequately pleaded scienter. There, plaintiffs averred that Matrixx's decision to withhold reports on adverse effects of its blockbuster product was intentional or at least deliberately reckless. *Matrixx Initiatives, Inc.*, 563 U.S. at 49. This inference was supported by many specific allegations. First, Matrixx had received multiple reports of the adverse effect in patients. *Id.* at 45-46. Second, the company had been alerted to prior studies demonstrating a biologically plausible link between the drug and the adverse health condition. *Id.* Third, Matrixx had pressured a physician into removing the drug's product name from his presentation on the adverse effect. *Id.* at 49. Fourth, the company categorically dismissed reports on a causal link as "completely unfounded and misleading," despite having insufficient scientific evidence to make that claim. *Id.* at 47. In its defense, Matrixx argued that "the most obvious inference is that [it] did not disclose the [reports] simply because [it] believed they were far too few . . . to indicate anything meaningful about adverse reactions to the use of [the product]." *Id.* at 49. The Supreme Court disagreed, concluding that the allegations, "taken collectively, give rise to a cogent and compelling inference that Matrixx elected not to disclose the reports of adverse events not because it believed they were meaningless but because it understood their likely effect on the market." *Id.* at 50 (internal quotations omitted).

In *Matrixx*, therefore, there was an obvious financial incentive not to disclose the reports, and there were specific allegations of behavior on the part of defendants which cut against the

non-fraudulent inference. Here, by contrast, the financial considerations weigh strongly in favor of a innocent explanation, given all defendants presumably stood to benefit financially from a successful NDA. Defendants' alleged "reckless gamble," on the other hand, came at a great cost and with no obvious upside for either the named defendants or the company. Moreover, the FAC's section on "additional scienter allegations" merely reiterates statements by Zogenix leadership showing that the FDA had "confirmed that a 505(b)(2) path for the NDA submission [was] acceptable." These statements do not, as the FAC suggests, constitute a promise on Zogenix's part to include 6- and 9-month historical fenfluramine toxicity studies in its NDA. That inference is assumed by plaintiffs but not supported by any of the quoted statements. *See, e.g.*, FAC ¶ 62 (Plaintiffs aver that "Zogenix management also told analysts that it would be filing the NDA under Section 505(b)(2) *in order to rely on the historical toxicity literature*," yet the quoted statement from Brean Capital, LLC is far less specific and cites the benefit of the 505(b)(2) pathway as allowing Zogenix to "reference *information* (mainly non clinical data) from the literature").

At bottom, the FAC is missing a critical link required to support the requisite inference of scienter. It does not plead with any specificity *how* defendants were supposed to have known that 6- and 9-month chronic toxicity data was the *sine qua non* of its NDA, the exclusion of which all but guaranteed rejection. If the FAC contained more than conclusory allegations on this point, perhaps an inference of scienter could be found, even absent a compelling motive. As is, however, "the inference of scienter here is weak, and certainly not as strong as the inference that Defendants had a non-fraudulent intent." *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 885 (9th Cir. 2012). Because the FAC fails to plead a "strong inference" of scienter as required under the PSLRA, defendants' motion to dismiss is also granted on this alternate and independent ground.

2. Count II – Section 20(a) of the Exchange Act

Section 20(a) of the Exchange Act makes certain "controlling" individuals also liable for violations of Section 10(b) and its underlying regulations. 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, 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).

There is no dispute that any liability under Section 20(a) in this action is dependent on the existence of an underlying violation of Section 10(b). In view of the dismissal of the 10(b) claims, this count must also be dismissed, with leave to amend.

V. CONCLUSION

For the foregoing reasons, defendants' first request for incorporation by reference or judicial notice for exhibits 1 through 13 is granted in part and denied in part. Defendants second such request is also granted in part and denied in part. Defendants' motion to dismiss is granted with leave to amend. Any amended complaint shall be filed within 21 days of the date of this order.

IT IS SO ORDERED.

Dated: January 24, 2020

RICHARD SEEBORG
United States District Judge

United States District Court
Northern District of California