UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD RICE, AS TRUSTEE OF THE RICHARD E. AND MELINDA RICE REVOCABLE FAMILY TRUST 5/9/90, and CHRISTIAN STANKEVITZ, *individually and on behalf of all others similarly situated*,	21-cv-0036 (LJL)
Plaintiffs,	OPINION AND ORDER
-v-	
INTERCEPT PHARMACEUTICALS, INC., MARK PRUZANSKI, and SANDIP S. KAPADIA,	
Defendants.	

LEWIS J. LIMAN, United States District Judge:

Defendants Intercept Pharmaceuticals, Inc. ("Intercept"), Mark Pruzanski, and Sandip S. Kapadia (collectively, "Defendants") move, pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act, 15 U.S.C. § 78u–4, to dismiss the first amended complaint (the "Complaint") of lead plaintiff Richard Rice as Trustee of the Richard E. and Melinda Rice Revocable Family Trust 5/9/90 and plaintiff Christian Stankevitz, individually and on behalf of all others similarly situated (collectively, "Plaintiffs"). Dkt. No. 67. Plaintiffs bring a putative securities class action claim alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. Dkt. No. 64.

For the following reasons, the motion to dismiss is granted.

BACKGROUND

The following facts are set forth in the Complaint, Dkt. No. 64 ("FAC") and are taken as true for purposes of this motion.

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases. FAC ¶¶ 3, 27. Defendants Mark Pruzanski, M.D. ("Pruzanski") and Sandip Kapadia ("Kapadia") were Intercept executives during the relevant time period. *Id.* ¶¶ 24–25. Pruzanski is one of Intercept's co-founders and served as Intercept's President and Chief Executive Officer from the company's inception in 2002 until January 1, 2021; he was also a director of the company's board at all relevant times. *Id.* ¶ 24. Kapadia was Intercept's Chief Financial Officer and Treasurer from July 2016 until March 26, 2021. *Id.* ¶ 25. Intercept's only drug, branded under the name Ocaliva, is obeticholic acid ("OCA"). *Id.* ¶¶ 4, 27. OCA targets the FXR receptor in the liver that regulates bile acid pathways; FXR engagement is believed to be critical to successfully treat pathologic injury due to progressive underlying disease. *Id.* ¶¶ 29, 31.

In May 2016, Intercept obtained FDA approval to market OCA for the treatment of primary biliary cholangitis ("PBC"), a liver disease that was estimated to affect 290,000 people worldwide and that leads to the progressive destruction of the bile ducts in the liver, which can cause inflammation, scarring, and cirrhosis. *Id.* ¶¶ 4, 32. Intercept later sought to have the same drug approved as a treatment for nonalcoholic steatohepatitis ("NASH"), a liver disease that impacts tens of millions of potential patients—it is estimated that between three percent to five percent of the world's population has NASH—and has no approved drug treatments. *Id.* ¶¶ 4, 37. NASH is a progressive liver disease caused by excessive fat accumulation in the liver that induces chronic inflammation, resulting in progressive fibrosis (scarring). *Id.* ¶ 38. Intercept's REGENERATE study aimed to evaluate the safety and efficacy of OCA in adult patients with NASH and liver fibrosis without cirrhosis. *Id.* ¶ 39.

I. Safety Issues with the Use of OCA for PBC

After OCA was approved by the FDA for the treatment of PBC, Intercept, in the course of its post-marketing pharmacovigilance activities, found that deaths had been reported in PBC patients with moderate or severe hepatic impairment. *Id.* ¶ 34. Intercept performed an analysis, in consultation with the FDA, and concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose for such patients. *Id.* As a result, in September 2017, Intercept issued a Dear Health Care Provider Letter.[1] *Id.* Additionally, in February 2018, the FDA updated the Ocaliva label in the United States to include a boxed warning and a dosing table and issued an updated drug safety communication to accompany the revised label. *Id.* ¶ 35. After these updates, Intercept continued to monitor the effects of OCA on their PBC patients. *Id.* ¶ 41.

There were also reports of several active liver toxicity signals in patients using OCA for treatment of PBC that were not already cited on Ocaliva's label. *Id.* ¶ 42. The FDA has a publicly available database that contains information on serious adverse event ("SAE") and medication error reports submitted to the FDA, called the FDA Adverse Event Reporting System

[1] A "Dear Healthcare Provider" letter is correspondence—often in the form of a mass mailing from the manufacturer or distributor of a human drug or biologic or from the FDA—intended to alert physicians and other health care providers about important new or updated information regarding a human drug or biologic. *See* Dear Health Care Provider Letters: Improving Communication of Important Safety Information, FDA, *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dear-health-care-provider-letters-improving-communication-important-safety-information (last updated Apr. 10, 2019). The letter "warn[ed] providers against prescribing late-stage PBC patients with a dose higher than recommended," and "explained that Intercept had received reports of '[l]iver injury, liver decompensation, liver failure, and death' after patients had taken incorrect does," and "that some early-stage PBC patients reported serious liver adverse events." *Hou Liu v. Intercept Pharmaceuticals, Inc.*, 2020 WL 1489831, at *3 (S.D.N.Y. Mar. 26, 2020). "Intercept urged healthcare providers to ensure that patients with late-stage PBC received the correct drug dose and to monitor all Ocaliva patients for liver-related adverse reactions." *Id.*

("FAERS"). *Id.* ¶ 43 & n.11. An analysis of reports in that database shows two liver toxicity signals that were not cited on the drug's label, among others that were included on the label[2]:

Most frequently reported adverse events for Ocaliva in the hepatobiliary system organ				
Adverse event	**US label status**	**Cases (primary)**	**ROR[3]**	**Event type**
Hepatorenal syndrome	Not labelled	6	5.08	Serious
Autoimmune hepatitis	Not labelled	6	1.83	Serious

Id. ¶ 43. The six hepatorenal events all occurred before the start of the class period, but the Complaint does not allege when precisely they occurred or were reported, nor does it provide any information about when the autoimmune hepatitis events occurred. *Id.* ¶ 47.

II. Events During the Class Period

The alleged securities fraud runs from September 27, 2019 to October 8, 2020, inclusive (the "Class Period"). *Id.* ¶ 2.

The Class Period begins on September 27, 2019, when Intercept announced that it had submitted a New Drug Application ("NDA") to the FDA for use of OCA in patients with fibrosis due to NASH. *Id.* ¶ 54.

[2] The Complaint alleges that there were five categories of adverse events that were not included on the label. FAC ¶ 43. However, Defendants pointed out in their briefing and Plaintiffs conceded at oral argument that three out of the five were in fact included on the label, and that of the adverse events listed in the table in paragraph forty-three, only autoimmune hepatitis and hepatorenal syndrome were not included on the label. Transcript of February 16, 2022 Oral Argument ("Oral Argument Tr.") at 25–26. Plaintiffs further indicated that they "will have to amend this complaint if you allow it to go forward . . . because it is true that some of the SAEs, which we believed had not been labeled and had not been disclosed, appeared to have been labeled, and we have to obviously deal with that." *Id.* at 17. Consequently, the Court considers only the allegations with respect to the SAEs that were not included on the label and disregards the allegations with respect to chronic hepatic failure, hepatic failure, and portal hypertension, which the parties agree were included on the label.

[3] ROR stands for "risk odds ratio." FAC ¶ 45.

On November 25, 2019, Intercept disclosed that the FDA had accepted its NDA for OCA seeking accelerated approval for treatment of fibrosis due to NASH and had granted priority review. *Id.* ¶ 56. Intercept also disclosed that the FDA had assigned a Prescription Drug User Fee Act ("PDUFA") target action date of March 26, 2020 for the NDA; PDUFA dates are deadlines for the FDA to review new drug applications. *Id.* ¶ 56 & n.15. The FDA indicated in the NDA filing acceptance notification letter to Intercept that it planned to hold an advisory committee meeting ("AdCom") to discuss the application. *Id.* ¶ 56.

On December 13, 2019, Intercept announced that the FDA had tentatively scheduled the AdCom for April 22, 2020; it anticipated that the FDA accordingly would extend the March 26, 2020 PDUFA target date for its NDA. *Id.* ¶ 57. On January 17, 2020, Intercept announced that the FDA had officially extended its PDUFA date for the NDA by three months to June 26, 2020. *Id.* ¶ 58.

On March 26, 2020, Intercept disclosed that the AdCom, which had been tentatively scheduled for April 22, 2020, had been postponed and was now tentatively scheduled for June 9, 2020. *Id.* ¶ 59. It further explained that it continued to work closely with the FDA on its priority review application and that the PDUFA target action date remained June 26, 2020. *Id.*

In May 2020, the FDA informed Intercept that it had identified a Newly Identified Safety Signal ("NISS") with Ocaliva; the FDA informed Intercept that its review was focused on a subset of the cirrhotic, or more advanced, PBC patients. *Id.* ¶ 48. The FDA classified the NISS as a "potential risk." *Id.* ¶ 63. The Complaint does not specify when in May this occurred.

On May 22, 2020, Intercept disclosed that the FDA had notified Intercept that it was postponing the AdCom for Intercept's NASH NDA to allow for the review of additional data the agency had requested. *Id.* ¶ 65. Pruzanski represented that Intercept was engaged in a dialogue

with the FDA and stated that "we believe that the additional data being submitted will be important in facilitating a more informed discussion at the AdCom" and that "[w]e remain confident in our NDA submission." *Id.* ¶ 20. After this disclosure, Intercept's share price fell $11.18, or 12.19%, to close at $80.51 per share on May 22, 2020, on unusually heavy trading volume. *Id.* ¶ 9.

On June 29, 2020, Intercept announced that the FDA had issued a Complete Response Letter ("CRL") regarding the NASH NDA that "indicated that, based on the data the FDA has reviewed to date, the [FDA] has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH." *Id.* ¶ 67. Intercept did not mention the NISS related to use of OCA in cirrhotic PBC patients during this disclosure. *Id.* After this disclosure, Intercept's share price fell $30.79, or 49.73%, to close at $46.70 per share on June 29, 2020, on unusually heavy trading volume. *Id.* ¶ 11.

Intercept disclosed the NISS and FDA review in pages fifty-seven and sixty-four of their August 10, 2020 quarterly report. *Id.* ¶ 69. After discussing the earlier review of reported deaths in patients taking OCA for PBC and the updates to the label, dosing table, and drug safety communication, the report stated:

> The FDA has notified us that in the course of its routine safety surveillance, in May 2020 the FDA began to evaluate a newly identified safety signal regarding liver disorder for Ocaliva which the FDA classified as a potential risk. Pursuant to FDA guidance, this does not mean that the FDA has concluded that the drug has the listed risk or that the FDA has identified a causal relationship between Ocaliva and the potential risk. As part of our routine pharmacovigilance efforts, we have worked with the FDA to reconcile our internal safety database with the FDA Adverse Event Reporting System database and have been conducting additional signaling analysis and monitoring activities. Any safety concerns associated with Ocaliva, perceived or real, or future label changes required by the FDA or other relevant regulatory

> authorities may materially and adversely affect our Ocaliva commercialization efforts and, consequently, our financial condition and results of operations.

Id. Intercept did not address the NISS in its press release or earnings call regarding its quarterly results. *Id.* ¶ 70.

The Complaint alleges that "[i]t was not until months later that someone noticed the change in the Company's boilerplate disclosures (where the language had been included) and tweeted about it," and that "even then, it took an article published by Stat+ . . . for the market to realize that the FDA was investigating the NISS." *Id.*

On October 8, 2020, the end date for the Class Period, Stat+ published an article entitled "FDA investigating whether Intercept Pharma drug is tied to potential liver injury risk." *Id.* ¶ 71. The article discussed the NISS and stated:

> Intercept has not previously said anything publicly about the FDA examination. Instead, the company chose to disclose the inquiry by adding several new sentences to an existing risk-statement paragraph on the 57th page of its most recent quarterly report filed with the Securities and Exchange Commission. The change was picked up by a health care investor on Twitter earlier this week.

Id. After the article, Intercept's share price fell $3.30, or 8.05%, to close at $37.69 per share on October 8, 2020, on unusually heavy trading volume. *Id.* ¶ 14

III. Events After the Class Period

On November 9, 2020, Intercept addressed the NISS during an earnings call with investors and analysts. *Id.* ¶ 73. Pruzanski stated that there was a twelve-month timeline for evaluation of this kind of NISS, and that "this potential Ocaliva risk in PBC was identified in the course of the FDA's routine safety monitoring activities based on a search of the FAERS database and other available external sources." *Id.*

PROCEDURAL HISTORY

The original complaint in this action was filed on November 5, 2020. Dkt. No. 1.

On January 25, 2021, the Court issued an Opinion and Order appointing Richard Rice as Trustee of the Richard E. and Melinda Rice Revocable Family Trust 5/9/90 to serve as lead plaintiff. Dkt. No. 53.

On March 15, 2021, Plaintiffs filed the Complaint. Dkt. No. 64.

Defendants filed this motion to dismiss the Complaint on April 26, 2021. Dkt. No. 67. Plaintiffs filed a response on May 26, 2021. Dkt. No. 70. Defendants filed a reply on June 9, 2021. Dkt. No. 68. The Court held oral argument on the motion on to dismiss on February 16, 2022.

LEGAL STANDARD

I. Federal Rules of Civil Procedure 12(b)(6)

On a 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and draw all possible inferences from those allegations in favor of the plaintiff. *See York v. Ass'n of the Bar of the City of New York*, 286 F.3d 122, 125 (2d Cir. 2002), *cert. denied*, 537 U.S. 1089 (2002). This requirement "is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Thus, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

A complaint must offer more than "labels and conclusions," or "a formulaic recitation of the elements of a cause of action" or "naked assertion[s]" devoid of "further factual enhancement" in order to survive dismissal. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 557 (2007). The ultimate question is whether "[a] claim has facial plausibility, [i.e.] the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. Put another way, the

plausibility requirement "calls for enough fact to raise a reasonable expectation that discovery will reveal evidence [supporting the claim]." *Twombly*, 550 U.S. at 556; *see also Matrixx Initiatives v. Siracusano*, 563 U.S. 27, 46 (2011).

II. Federal Rule of Civil Procedure 9(b)

A claim for fraud is subject to the particularity requirements of Federal Rule of Civil Procedure 9(b). A plaintiff must "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent; (2) identify the speaker; (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 187 (2d Cir. 2004); *see also Caputo v. Pfizer, Inc.*, 267 F.3d 181, 191 (2d Cir. 2001) (stating that to plead fraud with particularity, a complaint must "specify the time, place, speaker, and content of the alleged misrepresentations" and "should explain how the misrepresentations were fraudulent"). Allegations that are "conclusory and unsupported by assertions of fact" are not sufficient to meet the Rule 9(b) standard. *Luce v. Edelstein*, 802 F.2d 49, 54 (2d Cir. 1986).

III. The PSLRA

The Private Securities Litigation Reform Act ("PSLRA") imposes additional requirements on a plaintiff bringing a private securities fraud action. Plaintiff must "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u–4(b)(1). Plaintiff cannot plead "the materiality of the alleged misstatements or omissions . . . in a conclusory or general fashion." *In re JP Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595, 626 (S.D.N.Y. 2005) (citation omitted); *see In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 367 (E.D.N.Y. 2013) ("The materiality of allegedly false financials may not be pled in a conclusory or general fashion."). "[P]laintiffs 'must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how

that is so.'" *Okla. Firefighters Pension & Ret. Sys. v. Xerox Corp.*, 300 F. Supp. 3d 551, 564 (S.D.N.Y. 2018), *aff'd sub nom. Ark. Pub. Emps. Ret. Sys. v. Xerox Corp.*, 771 F. App'x 51 (2d Cir. 2019) (citation omitted).

In addition, where scienter is at issue, the plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the requisite state of mind." 15 U.S.C. § 78u–4(b)(2). Under this heightened pleading standard for scienter, a "complaint will survive . . . 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." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). In determining whether a strong inference exists, the allegations are not to be reviewed independently or in isolation, but the facts alleged must be "taken collectively." *Id.* at 323.

IV. Judicial Notice and Incorporation by Reference

Two separate rules permit the Court to consider documents that are not contained within the four corners of the complaint. *See Tellabs*, 551 U.S. at 322–23 (stating that, on a motion to dismiss, "courts ordinarily examine . . . documents incorporated into the complaint by reference, and matters of which a court may take judicial notice").

First, under Federal Rule of Evidence Rule 201, the Court may take judicial notice of a fact that is "not subject to reasonable dispute because it (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201. Under that rule, in federal securities fraud cases, courts can consider "public disclosure documents required by law to be filed, and actually filed, with the SEC." *Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991). Moreover, under this doctrine, the court need not limit itself to "documents attached to the complaint as exhibits or incorporated in the complaint by reference." *Id.* at 773.

Thus, as long ago as 1991, in *Kramer*, the Second Circuit held that it was proper, in a case where the plaintiff alleged misrepresentations in an offer to purchase, for the court to take judicial notice of related documents, such as the joint proxy statement that placed statements in the offer to purchase in context. The court reasoned, in part: "Were courts to refrain from considering such documents, complaints that quoted only selected and misleading portions of such documents could not be dismissed even though they would be doomed to failure. Foreclosing resort to such documents might lead to complaints filed solely to extract nuisance settlements." *Id.* at 774. *Kramer* remains good law today. *See, e.g.*, *Gamm v. Sanderson Farms, Inc.*, 944 F.3d 455, 462 (2d Cir. 2019) (stating that, on motion to dismiss, court may consider "public disclosure documents filed with the SEC"); *Staehr v. Hartford Financial Services Group, Inc.*, 547 F.3d 406, 425 (2d Cir. 2008) (court may take judicial notice of regulatory filings); *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007) ("[W]here public records that are integral to a fraud complaint are not attached to it, the court, in considering a Rule 12(b)(6) motion, is permitted to take judicial notice of those records.").

Second, relying on Federal Rule of Civil Procedure Rule 10(c), the Second Circuit has long held that a complaint "is deemed to include any written instrument attached to it as an exhibit or any statements or documents incorporated in it by reference," and that a court may consider documents incorporated in a complaint by reference on a motion pursuant to Federal Rule of Civil Procedure 12(b)(6) without converting it to a motion for summary judgment pursuant to Federal Rule of Civil Procedure 56. *Cortec Indus Inv. v. Sum Holdings*, 949 F.2d 42, 47 (2d Cir. 1991); *see Nicosia v. Amazon.con, Inc.*, 834 F.3d 220, 230–31 (2d Cir. 2016) (stating that "statements or documents incorporated in [the complaint] by reference" are properly considered on motion to dismiss). Those same principles permit the court to consider on a

12(b)(6) motion to dismiss documents upon which the plaintiff relies in bringing suit, which are integral to the complaint, and as to which they had notice. *Cortec*, 949 F.2d at 48. Generally, for this rule to apply, the plaintiff must have relied on the document in drafting the complaint; notice and possession are not enough. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002).

Thus, combining both doctrines, "the Court may consider documents that are referenced in the complaint, documents that the plaintiffs relied on in bringing suit and that are either in the plaintiffs' possession or that the plaintiffs knew of when bringing suit, or matters of which judicial notice may be taken." *In re Bank of Am. AIG Disclosure Sec. Litig.*, 980 F. Supp. 2d 564, 570 (S.D.N.Y. 2013) (citing *Chambers*, 282 F.3d at 153).

DISCUSSION

"Section 10(b) of the Securities Exchange Act makes it unlawful for any person to 'use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.'" *Matrixx*, 563 U.S. at 37 (quoting 15 U.S.C. § 78j(b)). "SEC Rule 10b-5 implements this provision by making it unlawful to, among other things, 'make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.'" *Id.* (quoting 17 C.F.R. § 240.10b-5(b)). The Supreme Court has "implied a private cause of action from the text and purpose of § 10(b)." *Id.*

To succeed on their Section 10(b) and Rule 10b-5 claim, Plaintiffs must plead—and ultimately prove—"(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." *Id.* (internal quotation marks omitted) (quoting *Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)).

Plaintiffs' Section 10(b) and Rule 10b-5 claims center around the allegations that Defendants failed to disclose both the SAEs and the NISS. The Complaint offers two theories as to why this failure to disclose is actionable: first, that the undisclosed information was material to the safety and continued use of Ocaliva for treatment of PBC; and second, that the undisclosed information was material to the regulatory approval of Ocaliva for treatment of NASH. On this motion to dismiss, Defendants argue that Plaintiffs have failed to plead the elements of a material misrepresentation or omission, the element of scienter, and the element of loss causation. The Court addresses each of these in turn.

I. Material Misrepresentation or Omission

"The first element of a Section 10(b) and Rule 10b-5 securities fraud claim requires an actionable misstatement or omission." *In re Lululemon Securities Litig.*, 14 F. Supp. 3d 553, 572 (S.D.N.Y. 2014). "[T]here are two components to this requirement: the statement must be false, and the statement must be material." *Id.*

First, in terms of falsity, "Rule 10b-5 distinguishes between untrue *statements* of material fact and certain kinds of material *omissions*." *City of Westland Police and Fire Retirement Sys. v. MetLife, Inc.*, 129 F. Supp. 3d 48, 66 (S.D.N.Y. 2015). "A complaint alleging that a defendant made an untrue statement of a material fact must plead facts that, if true, are sufficient to show that the statement alleged was 'false *at the time it was made*' and must do so with sufficient particularity to satisfy Rule 9(b) and the PSLRA." *Hou Liu v. Intercept Pharmaceuticals, Inc.*, 2020 WL 1489831, at *5 (S.D.N.Y. Mar. 26, 2020). Regarding omissions, "[i]t bears emphasis that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material

information." *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 152 (2d Cir. 2013) (internal quotation marks omitted and alteration adopted) (quoting *Matrixx*, 563 U.S. at 44). "[F]or an omission to be considered actionable under § 10(b), the defendant must be subject to an underlying duty to disclose." *Levitt v. J.P. Morgan Securities, Inc.*, 710 F.3d 454, 465 (2d Cir. 2013). "A duty [to] disclose under Rule 10b-5 may arise either '(1) expressly pursuant to an independent statute or regulation; or (2) as a result of the ongoing duty to avoid rendering existing statements misleading by failing to disclose material facts.'" *Lululemon*, 14 F. Supp. 3d at 572 (quoting *Thesling v. Bioenvision, Inc.*, 374 F. App'x 141, 143 (2d Cir. 2010) (summary order)).

"Additionally, to be actionable under Section 10(b) and Rule 10b-5, the alleged misstatement or omission must be material." *Id.* A misstatement or omission is material if there is "a substantial likelihood that a reasonable person would consider the fact misstated or omitted important in connection with a contemplated securities transaction." *Id.*

The Complaint challenges a variety of statements by the Defendants; most, if not all, of these challenges are based on the failure to disclose first the SAEs and then the NISS.

A. Failure to Disclose the SAEs

The Complaint challenges a variety of statements by the Defendants about Ocaliva made before May of 2020, alleging that those statements are actionable for the sole reason that they "failed to disclose that there were several serious adverse events from OCA in PBC patients that were not already cited on Ocaliva's label and that these serious adverse events in patients taking the same drug was a material risk to the approval of the NASH NDA." FAC ¶¶ 80–96.

As noted above, although the Complaint alleges that there were five SAEs identified in the FAERs database but not disclosed on Ocaliva's label, the Defendants point out—and Plaintiffs concede—that in fact only two of these were not labeled. The Complaint provides

ROR scores for each of the SAEs it identifies, and explains the significance of those ROR scores:

> In terms of frequency of these events, the relevant metric is the risk odds ratio (ROR). An ROR score above 1 indicates a higher than expected reporting rate for a given adverse event, and while there is no widely accepted benchmark regarding the level triggering a safety signal many in the industry assume that results above 2.0 warrant attention . . . .

Id. ¶ 45 (quoting an article on evaluate.com). It then emphasizes again that "ROR scores above 2 warrant attention," but highlights that "scores of more than 18 and almost 9 for liver failure and portal hypertension, respectively, are staggering," and reasons that "[a]s such, it is absurd to think that the Company would not have been aware of these adverse events, and the others, for its lone-approved drug that was responsible for all of Intercept's revenue." *Id.* ¶ 46. Liver failure and portal hypertension, however, are among the SAEs that were in fact disclosed on Ocaliva's label. The two SAEs that were not disclosed are hepatorenal syndrome and autoimmune hepatitis. The Complaint alleges that there were six reported cases of hepatorenal syndrome, for an ROR score of 5.08, and six reported cases of autoimmune hepatitis, for an ROR score of 1.83—below the ROR score of two that the complaint alleges "warrants attention." *Id.* ¶¶ 43, 46.

Defendants first argue that the allegedly omitted SAEs are immaterial as a matter of law. Dkt. No. 68 at 29. *Matrixx*, a Supreme Court case addressing "the question whether a plaintiff can state a claim for securities fraud under § 10(b) . . . and . . . Rule 10b-5 based on a pharmaceutical company's failure to disclose reports of adverse events associated with a product if the reports do not disclose a statistically significant number of adverse events," provides the framework within which this Court analyzes whether Plaintiffs have adequately pled that the allegedly undisclosed SAEs of hepatorenal syndrome and autoimmune hepatitis were material. 563 U.S. at 30. There, the plaintiffs alleged that Matrixx, a pharmaceutical company, "failed to

disclose reports of a possible link between its leading product, a cold remedy, and loss of smell, rendering statements made by Matrixx misleading." *Id.* Matrixx argued that the "complaint does not adequately allege that Matrixx made a material representation or omission . . . because the complaint does not allege that Matrixx knew of a statistically significant number of adverse events requiring disclosure." *Id.* The Supreme Court declined to adopt that view, holding that "the materiality of adverse event reports cannot be reduced to a bright-line rule." *Id.* Instead, the Supreme Court noted that pharmaceutical manufacturers need not disclose all reports of adverse events, because "[a]dverse event reports are daily events in the pharmaceutical industry," and "[t]he fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event." *Id.* at 43–44. Rather, the relevant question "remains whether a *reasonable* investor would have viewed the nondisclosed information '"as having *significantly* altered the 'total mix' of information made available.'" *Id.* at 44 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988)). Accordingly, the *Matrixx* Court held that "the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy this standard. Something more is needed, but that something more is not limited to statistical significance and can come from 'the source, content, and context of the reports.'" *Id.*

The Supreme Court concluded that in *Matrixx* the "something more" was plausibly alleged; the case was not merely "about a handful of anecdotal reports," but rather the complaint alleged that "Matrixx received information that plausibly indicated a reliable causal link between [the drug] and anosmia." *Id.* That information included not only "reports from three medical professionals and researchers about more than 10 patients who had lost their sense of smell after using [the drug]," but also the fact that two doctors at the University of Colorado Health

Sciences Center "had presented their findings about a causal link between [the drug] and anosmia to a national medical conference devoted to treatment of diseases of the nose." *Id.* It "critically" included the fact two doctors "had also drawn Matrixx's attention to previous studies that had demonstrated a biological causal link between intranasal application of zinc and anosmia." *Id.* at 46. These allegations, the Court found, "suffice[d] to 'raise a reasonable expectation that discovery will reveal evidence' satisfying the materiality requirement." *Id.* (quoting *Twombly*, 550 U.S. at 556). The Court reasoned:

> The information provided to Matrixx by medical experts revealed a plausible causal relationship between [the drug] and anosmia. Consumers likely would have viewed the risk associated with [the drug] (possible loss of smell) as substantially outweighing the benefit of using the product (alleviating cold symptoms), particularly in light of the existence of many alternative products on the market. Importantly, [the drug] allegedly accounted for 70 percent of Matrixx's sales. Viewing the allegations of the complaint as a whole, the complaint alleges facts suggesting a significant risk to the commercial viability of Matrixx's leading product.

Id. at 46–47.

Applying the reasoning of *Matrixx* to the allegations in this case demonstrates that Plaintiffs have not plausibly alleged that the nondisclosure of two non-labelled SAEs—six cases of hepatorenal syndrome and six cases of autoimmune hepatitis—was material. As in *Matrixx*, "the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy this standard." 563 U.S. at 44. Unlike in *Matrixx*, however, the Complaint here does not contain any allegations constituting the "something more" that is "needed" to satisfy this standard. *Id.*

Plaintiffs attempt to make out that "something more" by including the ROR scores in the Complaint, arguing that "an unbiased third party has made a determination that the risk odds ratio for those SAEs were staggering and warranted attention," Dkt. No. 70 at 20 (citing FAC

¶¶ 43–46), and by arguing that "[t]he long term safety of OCA was material to the approval of the NASH NDA," *id.* at 21. These arguments are unavailing.

First, the Complaint itself undermines the significance of the ROR score for autoimmune hepatitis; it alleges that there were six reported cases of autoimmune hepatitis, for an ROR score of 1.83—a score that is below the ROR score of two that the Complaint alleges "warrants attention" and is far below the ROR scores of nine and eighteen that the Complaint calls "staggering." FAC ¶¶ 43, 46. For autoimmune hepatitis, therefore, any argument that that the ROR score provides the "something more" is discredited by the Complaint itself. With regard to hepatorenal syndrome, the only other undisclosed SAE identified here, the Complaint cites FAERS data that there were six reported cases of hepatorenal syndrome, for an ROR score of 5.08. *Id.* However, as Defendants point out in their briefing, half of these cases "were reported to the FDA in 2017, well before the FDA revised Ocaliva's label in February 2018."[4] Dkt. No. 68 at 18. In other words, the FDA was aware of three of these cases when it revised Ocaliva's label yet chose not to include hepatorenal syndrome on the warning label.

Plaintiffs argue that "the SAEs are material because they changed the 'total mix' of information available about the safety of OCA." Dkt. No. 70 at 21. That argument misstates the relevant test; any new piece of information will, by definition, "change[] the 'total mix' of information available," but that does not automatically make it material. The relevant inquiry is whether the nondisclosed information would be viewed by a reasonable investor "as having *significantly* altered the 'total mix' of information made available." *Matrixx*, 563 U.S. at 44 (quoting *Basic*, 485 U.S. at 232). Plaintiffs have alleged no facts indicating that these two

[4] As articulated above, because Plaintiffs reference and rely upon the FAERS data in bringing this suit, the Court may consider that publicly available data on this motion to dismiss. *See Cortec*, 949 F.2d at 48.

adverse events—one of which, by the metric articulated in the Complaint itself, did not "warrant attention," and one of which the FDA was aware of when creating a warning label for Ocaliva but chose not to include—were in any way causally linked to Ocaliva or otherwise material. The conclusory assertion that "[t]he long term safety of OCA was material to the approval of the NASH NDA" cannot fill this gap; not only have Plaintiffs failed to allege anything linking these SAEs in PBC patients to the FDA's considerations with regard to the NASH NDA, but Plaintiffs have also failed to plausibly allege that these SAEs had any significance as to the long-term safety of OCA at all.

Defendants also argue that allegations of failure to disclose the SAEs are not actionable "for the independent reason that they were disclosed to the FDA and readily accessible to the public on the FDA's website," Dkt. No. 68 at 29, because "[a]lthough the underlying philosophy of federal securities regulation is that of full disclosure, there is no duty to disclose information to one who reasonable should be aware of it." *In re Bank of America AIG Disclosure Securities Litigation*, 980 F. Supp. 2d 564, 576 (S.D.N.Y. 2013) (internal quotation marks omitted) (quoting *Siebert v. Sperry Rand Corp.*, 586 F.2d 949, 952 (2d Cir. 1978)). Because alleged omissions are not actionable where there is no duty to disclose the information, "[w]here allegedly undisclosed material information is in fact readily accessible in the public domain, . . . a defendant may not be held liable for failing to disclose this information." *Id.* (internal quotation marks omitted) (quoting *In re KeySpan Corp. Securities Litigation*, 383 F. Supp. 2d 358, 377 (E.D.N.Y. 2003)). As the Complaint makes clear, the SAEs it identifies come from the FDA's FAERS database, FAC ¶ 43; as both parties acknowledge, the FAERS database is publicly available, *see* Dkt. No. 68 at n.6; Dkt. No. 70 at 22.

Plaintiffs respond that this public access does not preclude their claim because, as *In re MBIA, Inc., Securities Litigation* notes, "the Second Circuit has stressed that such corrective information must be conveyed to the public with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information created by alleged misstatements." *In re MBIA, Inc., Securities Litigation*, 700 F. Supp. 2d 566, 581–84 (S.D.N.Y. 2010). However, as in *Bank of America AIG Disclosure*, "the plaintiffs' reliance" on this doctrine "is misplaced," because the cases applying it, such as *MBIA*, "pertain[] to affirmative misstatements," whereas "[i]n this case, the plaintiffs do not allege any affirmative misstatement but rather allege that there were omissions in defendants' public disclosures." 980 F. Supp. 2d at 577. "Accordingly, this is not a case where prior misstatements had to be corrected with the same intensity and credibility as the original misstatements." *Id.* Plaintiffs also cite to a June 2020 opinion in *In re Acadia Pharmaceuticals Inc. Securities Litigation* rejecting the defendants' argument that "FAERS data cannot give rise to a claim for fraud by omission because the data was public record and investors were presumed to have access to it." 2020 WL 2838686, at *6 (S.D. Cal. June 1, 2020). The court provided two reasons for rejecting this argument: first, that "Defendants' assertion of the truth on the market defense at this stage is inappropriate"; and second, that "FAERS data files only contain raw data and a simple search of FAERS data cannot be performed with these files by persons who are not familiar with creation of relational databases," there were no facts indicating that the plaintiff was a sophisticated investor in the pharmaceutical industry, and the FAERS data was not referenced in the defendants' public disclosures. *Id.* (internal citations and quotation marks omitted). This citation too is unavailing; in a subsequent March 29, 2021 opinion, the same court "deem[ed] it appropriate to reconsider its prior findings," and held that "[r]egardless of Plaintiff's sophistication to navigate the FAERS

data, the FAERS data is public information and an efficient market incorporates 'all publicly available information.'" *In re Acadia Pharmaceuticals Inc. Securities Litigation*, No. 18-cv-01647-AJB-BGS (S.D. Cal. Mar. 29, 2021), ECF No. 101 (quoting *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 975–76 (9th Cir. 1999)).

B. Failure to Disclose the NISS

The Complaint also challenges a variety of statements by Defendants about Ocaliva made in and after May 2020, alleging that those statements are actionable because "they failed to disclose that the FDA had informed the Company that the agency had identified the NISS with Ocaliva related to liver disorder and was going to investigate the risk, that this investigation created a substantial, undisclosed risk to Intercept's future revenue from Ocaliva sales to PBC patients and business, and that the serious adverse events that led to this investigation and the investigation itself were material risks to approval of the NASH NDA." FAC ¶¶ 97–112.

Defendants' first challenge to this allegation is that, as the Complaint alleges, they disclosed the NISS investigation in their next quarterly filing on August 10, 2020, and that even if they had a duty to disclose the NISS, they had no duty to disclose it "'promptly' because courts recognize that companies 'are permitted a reasonable amount of time to evaluate potentially negative information and to consider appropriate responses before a duty to disclose arises.'" Dkt. No. 68 at 20 (quoting *In re Elan Corp. Securities Litigation*, 543 F. Supp. 2d 187, 217 (S.D.N.Y. 2008)). *In re Elan* involved a biotechnology company that announced on February 28, 2005 that they were halting ongoing clinical trials of their drug and suspending sales of the drug indefinitely "due to one confirmed, fatal case and one suspected, nonfatal case" of a rare and serious disease in patients participating in the drug's clinical trials. *Id.* at 198. The first case was diagnosed on February 7, 2005, and the defendants stated that they first learned of the two cases on February 18, 2005. *Id.* at 217. The court concluded, in the context of its

scienter analysis, that the complaint alleged "no facts indicating that Defendants acted with scienter to conceal the . . . diagnosis after [February 7, 2005] by waiting until February 28, 2005 to disclose the two . . . cases," because they "are permitted a reasonable amount of time to evaluate potentially negative information and to consider appropriate responses before a duty to disclose arises." *Id.* The court found that rather than a strong inference of scienter, "[a]n alternative and much more reasonable inference is that Defendants used this time to investigate, to gather more information, and to confer with [another biotechnology company with which they were partnered] and the FDA before taking any action." *Id.*

In re Elan differs from this case in two significant ways: (1) the *In re Elan* defendants disclosed the cases approximately three weeks after the first diagnosis and only ten days after they first learned of the diagnosis, whereas Intercept waited from sometime in May 2020 to August 12, 2020—over two months—to disclose the NISS; and (2) the *In re Elan* defendants delayed in disclosing two cases of a disease in patients in its clinical trials, something that by its nature has only an uncertain link with the drug being taken and therefore necessarily requires investigation, whereas Intercept delayed in disclosing that the FDA had identified a NISS with Ocaliva, a concrete event with a direct link to the drug. The Court thus rejects this argument; if Intercept had a duty to disclose the NISS, the facts alleged in the Complaint do not establish that it was entitled to wait over two months after receiving the notification from the FDA before making such disclosure.

Next, for an actionable claim to lie for failure to disclose the NISS, the fact that the FDA had identified a NISS must be material. The Complaint outlines two theories as to materiality of the NISS: (1) "that this investigation created a substantial, undisclosed risk to Intercept's future revenue from Ocaliva sales to PBC patients and business," and (2) "that the serious adverse

events that led to this investigation and the investigation itself were material risks to the approval of the NASH NDA." FAC ¶¶ 102, 108, 112. In other words, the NISS was material to the future of Ocaliva with regard to PBC as well as to the pending NASH NDA.

Plaintiffs' briefing explains that "NISS are SAEs, medication errors or adverse events that suggest therapeutic inequivalence or quality issues that warrant further investigation." Dkt. No. 70 at 2 n.2. The critical question, therefore, is whether under the *Matrixx* analysis the NISS would be viewed by a reasonable investor "as having *significantly* altered the 'total mix' of information made available," *Matrixx*, 563 U.S. at 44 (quoting *Basic*, 485 U.S. at 232)—whether the fact that the FDA identified a NISS itself constitutes the "something more" in addition to reports of SAEs that is needed to satisfy the materiality standard.

First, with regard to the materiality of the NISS to Ocaliva's use for treatment of PBC, Intercept emphasizes that "[t]he NISS was classified as a 'potential' risk (FAC ¶ 63), which is the *lowest* level of concern, and does not mean that the FDA had identified a causal relationship between Ocaliva and the 'liver disorder.'" Dkt. No. 68 at 7. The FDA's Center for Drug Evaluation and Research describes the levels of risk classification in its Manual of Policies and Procedures: "A NISS can be initially classified in three ways: as a *potential risk*, an *important potential risk*, or an emergency. If the currently available information suggests that a potential risk has or could have a negative impact on public health or has a negative impact on the benefit–risk profile of a drug, the risk will be considered an *important potential risk*." Dkt. No. 69-19 at 8.[5] The manual further defines a potential risk as "[a]n untoward occurrence for which there is

[5] For the purposes of resolving this motion to dismiss, the Court may take judicial notice of the Manual of Policies and Procedures, a document issued by a governmental agency. *See, e.g.*, *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 401 n.2 (S.D.N.Y. 2013) ("For the purpose of resolving the present motion, the Court takes judicial notice of public records contained on the FDA website.").

some basis for suspicion of an association with the medicinal product of interest, but where this association has not been confirmed." *Id.* at 15. Based on this, Intercept argues that the NISS "in and of itself does not mean that there is evidence of any causal link between the drug and safety at all." Oral Argument Tr. at 4.

The *Matrixx* test speaks to a spectrum of situations in which serious adverse events may or may not be material. On one end of the spectrum, as set forth above, *Matrixx* rejects the notion that serious adverse events on their own are material; "the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy this standard." *Matrixx*, 563 U.S. at 44. On the other end of the spectrum, *Matrixx* also rejects the categorical rule proposed by the defendants there that "reasonable investors would not consider [SAE] reports relevant unless they are statistically significant because only then do they 'reflect a scientifically reliable basis for inferring a potential causal link between product use and the adverse event,'" *id.* at 40; in so doing, the *Matrixx* Court emphasized that the FDA "sometimes acts on the basis of evidence that suggests, but does not prove, causation," *id.* at 42. Inherent in the reasoning of *Matrixx* is the notion that concrete, statistically significant evidence proving a causal link is not required, and evidence suggesting causation may be enough that "a reasonable investor would have viewed the nondisclosed information 'as having *significantly* altered the "total mix" of information made available.'" *Id.* at 44 (quoting *Basic*, 485 U.S. at 232). *Matrixx* does not require concrete proof of a causal relationship—only evidence of a "plausible causal relationship." *Id.* at 46–47.

The Court has already rejected the argument that the reported serious adverse events, standing alone, were material. A scenario where the only "something more" alleged is the fact that the FDA had identified "some basis for suspicion of an association with the medicinal

product of interest," does not provide much more evidence of a plausible causal link than the existence of the underlying serious adverse events does. The fact of the NISS—which was classified only as a potential risk, the lowest possible level—does not itself reflect that the FDA believes there is a plausible causal relationship or contain evidence that would support the existence of such a relationship; it represents only the desire to investigate whether it is plausible that such a relationship would exist. Indeed, because, as set forth above, the FDA did not classify the NISS as representing an "important potential risk," the document by definition did not even represent a view by FDA that "the currently available information suggests that a potential risk has or could have a negative impact on public health or has a negative impact on the benefit–risk profile of a drug." The FDA's classification of this as a potential risk, rather than an important potential risk, thus further demonstrates that the available underlying information and the NISS itself did not reflect any conclusion about a plausible link between the drug and liver disease, but rather only the desire to investigate further. The existence of serious adverse events always raises a question about whether the events are linked to the drug being taken; that question is not, in and of itself, material, and it does not become material simply because the FDA asks it. Rather, under *Matrixx*, it becomes material when there is some evidence—either from the FDA or some other source—suggesting a plausible causal relationship; while the results of the NISS investigation and the contents of any communication by FDA with regard to the NISS will certainly bear on that analysis, the bare fact of a NISS itself does not create that relationship.

With regard to the materiality of the NISS to Ocaliva's pending NASH NDA, the analysis is yet stronger. The FDA's identification and review of the NISS "was focused on a subset of the cirrhotic, or more advanced, PBC patients who have taken Ocaliva." FAC ¶ 63.

The NASH NDA was focused on noncirrhotic NASH—an entirely different liver disease. The NISS meant that the FDA had identified a set of serious adverse events in patients with cirrhotic PBC, which it believed raised "some basis for suspicion of an association" with the use of Ocaliva for treatment of PBC. On these facts alone, it raises *no* inference of any causal link between the SAEs in cirrhotic PBC patients and the use of Ocaliva for treatment of noncirrhotic NASH. The Complaint is devoid of any additional facts that could provide the basis for such an inference. Indeed, there are no allegations that even the FDA believed that the NISS was relevant to the pending NASH NDA. At oral argument, Plaintiffs, when asked "whether there is an allegation of fact from which an inference can be drawn that the FDA's actions with respect to OCA for NASH ha[d] anything to do with the NISS that was observed in patients taking the drug for PBS," conceded that they "don't believe that [they] have alleged affirmatively specific facts such as an insider or such as a report from the FDA that would say that the reason [they] are rejecting this new drug application is as a result of the issues that are raised by the NISS." Oral Argument Tr. at 18. Moreover, because the NISS was classified as a "potential risk" rather than an "important potential risk," while the FDA's identification of the NISS did reflect a suspicion that the underlying SAEs were linked to Ocaliva's use for treatment of PBC, it did not reflect a broader concern about the benefit–risk profile of the drug—the critical question the FDA was evaluating in context of the NASH NDA, *see* FAC ¶ 67—even for the use of that drug in cirrhotic PBC patients, let alone for the use of that drug in a completely different population of patients with noncirrhotic NASH. As such, there are no allegations from which the Court could conclude that a reasonable investor would consider the FDA's identification of a concern about a link between SAEs in patients taking Ocaliva for cirrhotic PBC and that use of the drug to

significantly alter the total mix of information about the likelihood of approval pending NDA for the use of that drug for treatment of noncirrhotic NASH.

Even assuming that the NISS was material, "[i]t bears emphasis that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information." *Kleinman*, 706 F.3d at 152 (internal quotation marks omitted and alteration adopted) (quoting *Matrixx*, 563 U.S. at 44). "[F]or an omission to be considered actionable under § 10(b), the defendant must be subject to an underlying duty to disclose." *Levitt v. J.P. Morgan Securities, Inc.*, 710 F.3d 454, 465 (2d Cir. 2013). "A duty [to] disclose under Rule 10b-5 may arise either '(1) expressly pursuant to an independent statute or regulation; or (2) as a result of the ongoing duty to avoid rendering existing statements misleading by failing to disclose material facts.'" *Lululemon*, 14 F. Supp. 3d at 572 (quoting *Thesling v. Bioenvision, Inc.*, 374 F. App'x 141, 143 (2d Cir. 2010)).

Defendants argue that the Complaint's allegations "do not cite any particularized facts supporting an inference that the FDA's decisions on the *noncirrhotic* NASH NDA were tied to its separate NISS investigation in a subset of patients with a different disease, PBC with advanced *cirrhosis*," and therefore that there was no duty to disclose the NISS in context of disclosures about the FDA's decision to postpone the AdCom for the NASH NDA and the CRL for the NASH NDA, because the NISS regarding PBC was not "sufficiently connected to defendants' existing disclosures to make those public statements misleading." Dkt. No. 68 at 23 (quoting *In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 403 (S.D.N.Y. 2016)). The Court addresses in turn whether each set of statements either contained affirmative misrepresentations or gave rise to a duty to disclose the NISS in order to make the statements not misleading.

1. May 11, 2020 Statements

The first set of challenged statements alleged in the Complaint were made on May 11, 2020, when Intercept issued a press release entitled "Intercept Pharmaceuticals Reports First Quarter 2020 Financial Results, and Provides Business Update," which included statements about the NASH NDA, including:

- "We have taken a number of important steps intended to ensure the integrity of our clinical trials, maintain continuity in our supply chain and advance our NASH launch preparation activities"; and
- "We remain very focused on the goal of bringing the first approved therapy to patients with advanced fibrosis due to NASH and expect to be well prepared for our upcoming FDA advisory committee meeting, which is tentatively scheduled for June 9, 2020."

FAC ¶ 97 (emphasis omitted). Additionally, the Complaint alleges that further statements were made by Defendant Pruzanski during an earnings call with analysts held on the same day, May 11, 2020; in response to a question about recent communications with the FDA, Pruzanski stated:

- "And then moving over to the safety side, there's overall exposure that we have. And then the safety topics that are well-known with respect to our drug that are in the literature. Pruritus being one, tolerability and then hepatic or more broadly hepatobiliary, and of course, the on-target lipid changes that we know very well. So those would be the anticipated topics there."

Id. ¶ 98. Last, on the same day, May 11, 2020, Intercept filed its quarterly report on Form 10-Q for the period ended March 31, 2020, which included various statements about the safety of Ocaliva, including:

- "In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. . . . We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate

> dosing in patients with advanced cirrhosis. These events and any safety concerns associated with Ocaliva, perceived or real, may adversely affect the successful development and commercialization of our product candidates and lead to a loss of revenues."
>
> - "Additional or unforeseen side effects relating to OCA or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. With the approval of Ocaliva for PBC in the United States, Europe and certain of our other target markets, OCA is currently used in an environment that is less rigorously controlled than in clinical studies. If new side effects are found, if known side effects are shown to be more severe than previously observed or if OCA is shown to have other unexpected characteristics, we may need to abandon our development of OCA for PBC, NASH and other potential indications. Furthermore, our commercial sales of Ocaliva for PBC may be materially and adversely affected."

Id. ¶¶ 99–101 (emphasis omitted).

The Complaint alleges that these statements "were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose that the FDA had informed the Company that the agency had identified the NISS with Ocaliva related to liver disorder and was going to investigate the risk, that this investigation created a substantial, undisclosed risk to Intercept's future revenue from Ocaliva sales to PBC patients and business, and that the serious adverse events that led to this investigation and the investigation itself were material risks to the approval of the NASH NDA." *Id.* ¶ 102.

The Complaint does not allege with specificity when in May 2020 the FDA informed Intercept of the NISS; it alleges only that "in May 2020, the FDA specifically informed Defendants that it had begun to evaluate a NISS regarding liver disorder for Ocaliva, which the FDA classified as a potential risk." *Id.* ¶ 63. Defendants assert in their memorandum in support of their motion to dismiss that the 10Q for the first quarter of 2020 was "filed *before* the May 2020 NISS investigation." Dkt. No. 68 at 33. Although the allegations of the Complaint must be

taken as true, the Complaint is silent as to when in May the FDA informed Intercept of the NISS. Its assertion that statements made on May 11 were therefore affirmatively false or misleading because they failed to disclose the NISS are wholly conclusory; there are no specific factual allegations in the Complaint that would support an inference that on May 11 Intercept knew of the NISS yet failed to disclose it.

2. May 22, 2020 Statements

The next set of challenged statements alleged in the Complaint were made on May 22, 2020, when Intercept issued a press release entitled "Intercept Provides Regulatory Update," in which Intercept provided an update on the FDA's tentative scheduling of the advisory committee meeting:

> - "Intercept Pharmaceuticals, Inc. (Nasdaq11CPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced that based on discussions earlier this week, the U.S. Food and Drug Administration (FDA) has notified Intercept that its tentatively scheduled June 9, 2020 advisory committee meeting (AdCom) relating to the company's new drug application (NDA) for obeticholic acid (OCA) for the treatment of liver fibrosis due to nonalcoholic steatohepatitis (NASH) has been postponed. *The postponement will accommodate the review of additional data requested by the FDA that the company intends to submit within the next week.* The FDA has indicated that it will reach out to Intercept in the near future with a new proposed AdCom date. Intercept now anticipates that the FDAs review of its NDA will extend beyond the Prescription Drug User Fee Act (PDUFA) target action date of June 26, 2020.
>
> 'While this delay was unanticipated, *following our most recent dialogue with the FDA we believe that the additional information being submitted will be important in facilitating a more informed discussion at the AdCom*,' said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. '*We remain confident in our NDA submission and look forward to continuing to work with the FDA to bring the first treatment to patients with advanced fibrosis due to NASH*.'"

FAC ¶ 103. Once again, the Complaint alleges that these statements were false and/or misleading for failure to disclose the NISS. The press release, however, did not purport to

review the safety of Ocaliva generally; instead, it provided a specific update with regard to the AdCom scheduling for the NASH NDA. Plaintiffs' allegations that these statements were misleading because they failed to mention the NISS therefore rely on the assumption that the NISS in PBC patients was relevant to the pending NASH NDA. At oral argument, Plaintiffs, when asked "whether there is an allegation of fact from which an inference can be drawn that the FDA's actions with respect to OCA for NASH ha[d] anything to do with the NISS that was observed in patients taking the drug for PBS," conceded that they "don't believe that we have alleged affirmatively specific facts such as an insider or such as a report from the FDA that would say that the reason we are rejecting this new drug application is as a result of the issues that are raised by the NISS." Oral Argument Tr. at 18. Absent any such allegations linking the NISS for PBC to the NASH NDA, the Complaint does not allege facts supporting their assertion that there was a duty to disclose the NISS in a press release exclusively about the NASH NDA, because there are no allegations that could support that the NISS for PBC was "sufficiently connected" to the disclosure about the NASH NDA so as "to make those public statements misleading." *Sanofi*, 155 F. Supp. 3d at 403.

3. June 29, 2020 Statements

Finally, the Complaint alleges that a third set of statements made on June 29, 2020, were false and misleading because they failed to disclose the NISS. Those statements all related to the FDA's CRL with regard to the NASH NDA, and included:

- The statement in a press release entitled "Intercept Receives Complete Response Letter from FDA for Obeticholic Acid for the Treatment of Fibrosis Due to NASH" that "[t]he CRL indicated that, based on the data the FDA has received to date, the Agency has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of liver fibrosis due to NASH."

- The statement by Defendant Pruzanski in a business update conference call with analysts to discuss the receipt of the CRL for the NASH NDA made in response to a question about what he believed had given the FDA pause about the risks of approval that "[o]n the safety side, the typical known profile of OCA that there is nothing substantively new in terms of safety issue that's arisen or that the agency has pointed to. And so, no, I don't think that there is anything there that's come up that that has figured into a fundamentally different view about benefit risk."

- The statement by Defendant Pruzanski during the same call, in response to a question about whether the FDA had mentioned anything about the safety of OCA in recent communications, that "[o]n the safety side, as I mentioned a couple of minutes ago, the safety issues are consistent with the known profile of OCA. There is nothing substantively new in terms of the safety issues flagged. And frankly, from our point of view, nothing that stands out as a showstopper, right? So we're not talking about something new on the safety side."

FAC ¶¶ 105–107. Defendants once again argue that these statements did not give rise to any duty to disclose the NISS because "[j]ust because a pharmaceutical company speaks about the development of its drug in a particular disease, it does not mean that the company has a duty to disclose 'any and all material information' about that drug's use in a *different* disease affecting a *different* therapeutic target 'that may be relevant or of interest to a reasonable investor.'" Dkt. No. 68 at 24 (quoting *Kleinman*, 706 F.3d at 152, 154–55). As with the May 22, 2020 statements, this argument is persuasive with respect to the statements about the NASH NDA in the press release. The press release was explicitly about the CRL for the NASH NDA; it made no reference to the use of Ocaliva in PBC patients and the Complaint alleges no facts suggesting a link between the NISS and the FDA's decision regarding the NASH NDA.

The statements on the earnings call present a closer question. In isolation, the alleged misstatements appear to refer to "the typical known profile of OCA" "on the safety side" generally. If there were nothing more, the statements could be read to assert that there is "nothing substantively new" in terms of the typical known safety profile of OCA with regard to any of the treatments for which it was approved or seeking approval. However, under the federal

securities laws, statements to investors are not read by isolating the part that is most supportive of the plaintiff's claim and divorcing it from the remainder that would put it in context. *See, e.g.*, *Gissin v. Endres*, 739 F. Supp. 2d 488, 512 (S.D.N.Y. 2010) (considering the fact that alleged misrepresentation was made "in the context of an earning conference call analyzing the financial quarter ending December 31, 2007" in determining that the statement "is appropriately grounded in accurate historical data"); *In re Supercom Inc. Securities Litigation*, 2018 WL 4926442, at *23 (S.D.N.Y. Oct. 10, 2018) (considering statement made on an earnings call "in its full context"). Statements are read in their entirety and as they would be read by the reasonable investor. *See In re Sketchers USA, Inc. Securities Litigation*, 444 F. Supp. 3d 498, 516 (S.D.N.Y. 2020) ("The key question in considering the misleading nature of a statement is 'whether defendants' representations, taken together and in context, would have misled a reasonable investor.'" (alteration adopted) (quoting *McMahan & Co. v. Wherehouse Ent. Inc.*, 900 F.2d 576, 579 (2d Cir. 1990)). Reading Pruzanski's comments in that manner, it is apparent that they do not refer generally to the safety of OCA in any application but specifically to the known safety profile of OCA with regard to its use for treatment of NASH. Pruzanski's first such statement is in response to the question:

> And then maybe on the safety side, if you could maybe help us understand whether – I guess, was there anything specific that sort of you believe maybe had given the FDA pause on benefit risk and how the imbalances in pancreatitis and gallstones in the interim REGENERATE data look in the updated results that you've submitted?

Dkt. No. 69-21. The question itself, in asking about the safety side, references the updated REGENERATE data provided to the FDA; the REGENERATE study aimed to evaluate the safety and efficacy of OCA in adult patients with noncirrhotic NASH. As such, the only reasonable inference is that when in his answer Pruzanski referred to the "the safety side" with respect to "the typical known profile of OCA," he was referred to the safety side for the

population of patients who would take OCA for NASH, *i.e.*, the REGENERATE data, and not safety in some more abstract or general sense. In other words, Pruzanski was asked a specific question about the safety data provided to the FDA about OCA's use in patients with noncirrhotic NASH, whether anything in that data may have given the FDA pause, and how the updated data looks, and Pruzanski responded in kind, answering the question by describing the safety profile of OCA with regard to NASH. Pruzanski's second reference to the "safety side" and the "known profile of OCA" appears in the same context, and specifically refers back to this first answer: "So . . . , on the safety side, as I mentioned a couple of minutes ago, the safety issues are consistent with the known profile of OCA." *Id.* As such, the context of the statements reveals that they were made in context of a call about the NASH NDA and in response to specific questions about the NASH NDA; they were not misleading for failure to disclose the NISS identified for PBC patients.

4. August 10, 2020 Statements

Plaintiffs also challenge statements on August 10, 2020 as misleading, again because they failed to disclose the NISS. However, as the Complaint acknowledges, Intercept's August 10, 2020 quarterly report did include language about the NISS. FAC ¶¶ 68–69. The August 10, 2020 quarterly report mentions the NISS twice; the first time is in a lengthy section under the heading "Risks Related to the Development and the Regulatory Review and Approval of Our Products and Product Candidates." Dkt. No. 69-8 at 47–63. On page fifty-seven of that section, it states: "The FDA has notified us that in the course of its routine safety surveillance, in May 2020 the FDA began to evaluate a newly identified safety signal regarding liver disorder for Ocaliva which the FDA has classified as a potential risk. Pursuant to FDA guidance, this does not mean that the FDA has concluded that the drug has the listed risk or that the FDA has identified a causal relationship between Ocaliva and the potential risk." *Id.* at 57. The report

mentions the NISS a second time in a section under the heading "Risks Related to the Commercialization of Our Products," *id.* at 63–71; on page sixty-four of that section, it contains the same statement, *id.* at 64.[6]

Plaintiffs assert, however, that despite this inclusion, Intercept "attempt[ed] to bury the news . . . by inserting language about the safety signal in the middle of boilerplate paragraphs deep in the quarterly report." FAC ¶ 69; *see also* Dkt. No. 70 at 17 ("[T]he statements appear on pages 57 and 63 of a 98-page quarterly report in the midst of a droning paragraph about general safety concerns and past FDA actions concerning OCA's safety."). Plaintiffs' citations to case law, however, do not suggest that including information in the middle of a quarterly report constitutes "burying" the information. In *Werner v. Werner*, for example, the Third Circuit noted that "[u]nder the 'buried facts' doctrine, a disclosure is deemed inadequate if it is presented in a way that conceals or obscures the information sought to be disclosed." 267 F.3d 288, 297 (3d Cir. 2011). It explained that "[t]he doctrine applies when the fact in question is hidden in a voluminous document or is disclosed in a piecemeal fashion which prevents a reasonable shareholder from realizing the 'correlation and overall import of the various facts interspersed throughout' the document." *Id.* (quoting *Kas v. Financial General Bankshares, Inc.*, 796 F.2d 508, 516 (D.C. Cir. 1986)). Ultimately, however, the Third Circuit concluded in *Werner* that the relevant information was "adequately disclosed" in several annual reports and a letter accompanying the first report, distinguishing other cases that "have applied the buried facts situation" in "situations where the manner of disclosure disguised or seriously distorted

[6] Plaintiffs assert that "[t]he only heading demarcating the information is "Risk Factors," a section that spans 54 pages of the filing." Dkt. No. 70 at 18. This is plainly contradicted by the filing; the "Risk Factors" section contains many sub-headings, including the two identified above, within which the NISS is discussed. *See supra* and Dkt. No. 69-8 at 40, 47, 63.

important information." *Id.* at 298 (citing cases where misleading information was prominently presented and important clarifications were presented separately and less prominently or where information was segmented into different parts in different places in a document). *In re Alstom SA*, in this District, did apply this doctrine, but not because the allegedly undisclosed information was included in a large document or even because it was included only in footnotes; rather, it found that the "two, non-consecutive" and "vaguely worded footnotes" did not contain "critical underlying information" and used language which made it "virtually impossible to discern what exactly the company is alluding to." 406 F. Supp. 2d 433, 453 & n.11 (S.D.N.Y. 2005). The disclosure was not insufficient simply because it was made in a multi-page document or in footnotes; it was insufficient because it did not adequately convey the information because of its language, because the information was segmented into non-consecutive footnotes, and because the disclosure omitted critical information.

In contrast, common sense suggests, as courts have recognized, that "'every fact cannot be contained in the beginning' of an SEC filing." *Ziebron v. Metaldyne Corp.*, 2010 WL 11544989, at *3 (E.D. Mich. Sept. 28, 2010) (quoting *Valley Nat'l Bank of Ariz. V. Trustee for Westgage-California Corp.*, 609 F.2d 1274, 1282 (9th Cir. 1979)). The mere fact that a disclosure is made in the middle of an SEC filing, rather than at the beginning, does not render that disclosure "buried." *See Chipman v. Aspenbio Pharma, Inc.*, 2012 WL 4069353, at *6 (D. Colo. Sept. 17, 2012) ("A disclosure is not 'buried' simply because it is included in a document properly incorporated by reference and/or situated in the middle of a multi-page document."). Here, the information about the NISS "was set out logically under appropriate headings, alongside related information," which "demonstrates that it was not impermissibly 'buried beneath other information,' as plaintiffs assert." *Singh v. Schikan*, 106 F. Supp. 3d 439, 448

(S.D.N.Y. 2015). "The defendants cannot be held liable for failing to disclose something that they disclosed." *Altayyar v. Etsy, Inc.*, 242 F. Supp. 3d 161, 180 (E.D.N.Y. 2017).

II. Scienter

"The PSLRA requires plaintiffs to state with particularity . . . the facts evidencing scienter, *i.e.*, the defendant's intention 'to deceive, manipulate, or defraud.'" *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 & n.12 (1976)); *see also* 15 U.S.C. § 78u–4(b)(2). "As set forth in § 21D(b)(2) of the PSLRA, plaintiffs must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Tellabs*, 551 U.S. at 314 (quoting 15 U.S.C. 78u–4(b)(2)). "To qualify as 'strong' within the intendment of § 21D(b)(2), . . . and inference of scienter must be more than merely plausible or reasonable . . . ." *Id.* A "complaint will survive . . . 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. "The inquiry . . . 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." *Id.* at 322–23.

A plaintiff can adequately plead scienter through particularized factual allegations either "(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 Communications, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007).

A. Motive to Commit Fraud

"'To satisfy motive and opportunity,' plaintiffs must allege that defendants 'benefitted in some concrete and personal way from the purported fraud.'" *Glaser v. The9, Ltd.*, 772 F. Supp.

2d 573, 586 (S.D.N.Y. 2011) (quoting *ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009)).

The Complaint alleges that Pruzanski, one of the individual defendants, "took advantage of the artificially inflated price of Intercept stock resulting from the false and/or misleading statements to sell a significant amount of his directly and indirectly owned shares in the weeks following the submission of the NDA." FAC ¶ 138. Specifically, it alleges that he made four stock sales during the class period—in November and December of 2019—amounting to a sale of 50,517 shares for over five million dollars in proceeds. *Id.* ¶ 139. It alleges that "[t]hese millions of dollars provided a very real incentive for Defendant Pruzanski to omit to disclose the material risks impacting approval of the NASH NDA." *Id.* ¶ 140.

"[M]otive can be shown . . . 'when corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit.'" *In re Citigroup Inc. Securities Litigation*, 753 F. Supp. 2d 206, 233 (S.D.N.Y. 2010) (quoting *ECA*, 553 F.3d at 198). "However, the mere fact that insider stock sales occurred does not suffice . . . , instead, plaintiffs must establish that the sales were 'unusual' or 'suspicious.'" *Glaser*, 772 F. Supp. 2d at 587 (internal quotation marks omitted and alterations adopted) (quoting *In re Gildan Activewear, Inc. Securities Litigation*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009)).

One critical consideration in determining whether stock sales are unusual are suspicious is the timing of the sales, including "whether sales occurred soon after statements defendants are alleged to know to be misleading," "whether sales occurred shortly before corrective disclosures or materialization of the alleged risk," and "whether sales were made pursuant to Rule 10b5-1 plans." *Id.* Additional "[f]actors considered in determining whether insider trading activity is unusual include the amount of profit from the sales, the portion of stockholdings sold, the change

in volume of insider sales, and the number of insiders selling." *In re Aratana Therapeutics Inc. Securities Litigation*, 315 F. Supp. 3d 737, 762 (S.D.N.Y. 2018) (quoting *In re Scholastic Corp. Securities Litigation*, 252 F.3d 63, 74–75 (2d Cir. 2001)). Consideration of these factors demonstrates that Plaintiffs have not alleged facts that would establish that Pruzanski's trades were unusual or suspicious.

First, as set forth above, the Complaint alleges that Pruzanski sold a total of 50,517 shares over the course of four stock sales in November and December of 2019. FAC ¶ 139. The first set of sales—on November 25 and November 26, 2019—occurred immediately after Intercept issued a 10-Q, when stock sales of insiders customarily take place, and all of them were close to the very start of the Class Period, September 27, 2019. They were far from the conclusion of the Class Period, October 8, 2020. The Complaint does allege three false or misleading statements in or before November 2019; these include a press release about the NASH NDA on September 27, 2019; the third quarter 2019 Form 10-Q report, along with a press release and earnings call about the report, on November 5, 2019; and a press release about the FDA accepting the NASH NDA for priority review, on November 25, 2019. *Id.* ¶¶ 80–90. It alleges that each of these statements were false or misleading "because they failed to disclose that there were several serious adverse events from OCA in PBC patients that were not already cited on Ocaliva's label and that these serious adverse events in patients taking the same drug was a material risk to approval of the NASH NDA." *Id.* ¶¶ 81, 88, 90. But, as noted, only two of those SAEs were not on the label and all of them were contained in a publicly available database. Tellingly, there were no sales proximate to the time Plaintiffs allege Intercept received the most material non-public information—after the FDA notified Intercept about the NISS in May 2020 or in the period from that notification until Intercept disclosed the NISS in August 2020. The other thrust

of Plaintiffs' Complaint relates to the risk to the approval of OCA for NASH, but Pruzanski's stock sales also occurred long before the CRL or the Complaint alleges that "[t]he truth regarding Intercept was partially revealed, and/or the concealed risks materialized, on or about: May 22, 2020; June 29, 2020; and October 8, 2020." *Id.* ¶ 114.

The timing of Pruzanski's stock sales thus does not suggest any unusual or suspicious behavior. He did not sell at the times one would have expected sales if Pruzanski was intending to take advantage of stock movements—for example, shortly before the disclosures in May 2020 and June 2020, or after Intercept learned of the NISS in May 2020 but before they disclosed it in August 2020. The Complaint does not allege facts supporting a conclusion that Intercept's stock prices were artificially inflated in November and December of 2019,[7] nor does it allege that the stock prices dropped shortly thereafter. As such, there is nothing about the timing of these trades suggesting unusual or suspicious activity.

Moreover, the relevant trades were all made pursuant to a Rule 10b5-1 trading plan. "[A]s a general matter, '[t]rades made pursuant to a Rule 10b5-1 trading plan do not give rise to a strong inference of scienter.'" *Aratana*, 315 F. Supp. 3d at 764 (quoting *Lululemon*, 14 F. Supp. 3d at 585). Plaintiffs argue that if a trading plan is "entered into during the Class Period, it would provide no defense to scienter allegations." Dkt. No. 70 at 31. While "[i]t is true . . . that the mere existence of a trading plan will not defeat an otherwise strong inference of scienter where, as here, the plans were entered into during the Class Period," *Aratana*, 315 F. Supp. 3d at 764, here the Complaint "pleads no facts that even remotely suggest that [Pruzanski] entered into

[7] The Complaint does contain various references throughout to "artificially inflated" stock prices, but it contains no specific factual allegations about the stock prices before the allegedly misleading statements or around the time of those statements to support these conclusory assertions.

the Plan 'strategically' so as to capitalize on insider knowledge," *Lululemon,* 14 F. Supp. 3d at 585; *see also Aratana*, 315 F. Supp. 3d at 764 ("But the AC fails to raise any inference that the plans were themselves suspect.").

Plaintiffs' allegations, and the documents incorporated by reference, are inconsistent with an inference of scienter. Pruzanski's first relevant SEC Form 4, filed on November 27, 2019, reflects that the transactions on November 25 and 26 were "effected pursuant to a pre-existing Rule 10b5-1 trading plan adopted by the reporting person." Dkt. No. 69-12 at 4–5. The SEC Form 4 for the December sales also reflect that they were effected pursuant to the Rule 10b5-1 trading plan. *Id.* at 6–7. Thus, the latest date the plan could have been entered into is November 25, 2019—the same day that Intercept disclosed that the FDA had accepted its NASH NDA and granted priority review, and long before Intercept was notified about the NISS or any delays in the FDA's processing of the NASH NDA. *See* FAC ¶¶ 56–59. If the plan had been entered into strategically to capitalize on insider knowledge and if, as Plaintiffs would have the Court accept, Pruzanski knew or believed the SAEs or the history of OCA posed an undisclosed threat to the approval of OCA for NASH or the marketing of OCA for PBC, one would have expected the plan to provide for extensive sales during the time period before which Intercept would receive negative regulatory news and the "gig would be up." The fact that the Rule 10b5-1 trading plan apparently did not provide for any sales later in the Class Period and that its timing does not appear to be positioned to capitalize on any material nonpublic information is inconsistent with an inference that it was entered into strategically in order to capitalize on insider knowledge.

Next, Plaintiffs do not allege Pruzanski's profits from the stock sales, including allegations about only the gross proceeds in the Complaint. FAC ¶ 139. The Complaint makes the conclusory assertion that "Defendant Pruzanski Profited Handsomely From Selling Intercept

Stock At Inflated Prices," *id.* at 42, but it contains no factual allegations regarding what those profits were. "Plaintiffs' failure to allege defendants' profits would itself be a sufficient basis to reject an inference of motive." *Aratana*, 315 F. Supp. 3d at 762 n.12 (citing *Glaser*, 772 F. Supp. 2d at 592). However, the Court takes judicial notice of Pruzanski's SEC Forms 4, Dkt. No. 69, Ex. 12, which "supply the missing information as to total holdings and profits," *Aratana*, 315 F. Supp. 3d at 762 n.12. Those forms demonstrate that from the four stock sales of a total of 50,417 shares, Pruzanski's profits totaled just under four and a half million dollars. Although this is a "handsome" sum, in context it is not a sum sufficient to give rise to an inference of scienter. *Cf. Lululemon*, 14 F. Supp. 3d at 585 (holding that alleged stock sales for a profit of $131 million still did not "give rise to a strong inference of scienter" when the trades were made pursuant to a 10b5-1 plan and there were no facts suggesting the plan itself was suspect); *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001) (noting that in earlier case, motive was sufficiently alleged where defendant sold "*80% of his holdings* for a substantial profit" (emphasis added)).

The SEC forms show that on October 3, 2019, before any of the stock sales referenced in the Complaint, Pruzanski directly owned 469,126 shares of common stock, Dkt. No. 69, Ex. 12 at 2–3; on January 3, 2020, after all of the stock sales referenced in the Complaint, Pruzanski directly owned of 466,829 shares of common stock, *id.* at 8–9. Throughout this time, Pruzanski also had indirect ownership of 100,000 additional shares. *Id.* at 2–3, 8–9. The 50,517 shares that Pruzanski sold thus represent approximately 10.76% of his pre-sale direct holdings, and 8.87% of his total pre-sale holdings. Although he may have netted approximately $4.5 million on the sales he made at the beginning of the Class Period, he lost far more on the shares he retained during the remainder of the class period.

Indeed, as Defendants emphasize, Pruzanski's holdings increased during the alleged Class Period. *See* Dkt. No. 69, Ex. 12 (showing that Pruzanski started with 470,673 directly held shares and ended up with 475,517 directly held shares, with the 100,000 indirectly held shares remaining consistent). As Plaintiffs point out, Pruzanski's January 27, 2020 Form 4 indicates that on January 23, 2020, he acquired 10,800 shares for free, which accounts for the increase in total holdings. *Id.* at 10–11. The parties disagree over whether this increase is significant; regardless, even if those shares are discounted, Pruzanski's holdings decreased by approximately 1.03% of the 470,673 directly held shares with which he entered the class period, and by approximately 0.85% of the total shares with which he entered the class period—both significantly below the 1.9% decrease in shares that another court in this district deemed "miniscule." *See Aratana*, 315 F. Supp. 3d at 763. Thus, even discounting the slight *increase* in total holdings, the "miniscule overall reduction" in Pruzanski's holdings once the 10,800 shares are set aside "undermine[s] an inference that defendants, thorough their sales, sought to capitalize on the necessarily time-limited artificial inflation of [Intercept]'s stock price." *Id.*; *see also Glaser*, 772 F. Supp. 2d at 593 ("It defies reason that an entity looking to profit on a fraudulently inflated stock price would hold close to ninety percent of its shares as prices fell, *while knowing that the information illuminating the fraud was seeping into the market*.").

Finally, the Complaint alleges stock sales only by Pruzanski; it does not allege similar sales by the other individual defendant, Kapadia, nor does it allege similar sales by any other insiders. Plaintiffs acknowledge this in their briefing only by arguing that "[a]t most, this fact would undermine an inference of scienter as to Kapadia only, not Pruzanski." Dkt. No. 70 at 32.

In sum, "the overall circumstances surrounding the individual defendants' sales . . . clearly do not plausibly support inferring scienter." *Aratana*, 315 F. Supp. 3d at 764. The timing

of the trades and of the entry into the Rule 10b5-1 trading plan are not consistent with an inference of scienter; neither the number of shares sold relative to Pruzanski's holdings nor the size of the decrease in his overall holdings during the Class Period suggest any unusual or suspicious activity; and there are no allegations of similar trades by other insiders.

B. Conscious Misbehavior or Recklessness

"Recklessness is generally established by a showing that 'defendants knew facts or had access to non-public information contradicting their public statements,' and therefore 'knew or should have known they were misrepresenting material facts.'" *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 601 (S.D.N.Y. 2016) (quoting *In re Scholastic Corp. Securities Litigation*, 252 F.3d 63, 76 (2d Cir. 2001)). "Where, as here, a motive to defraud is not adequately pled, a plaintiff 'must produce a stronger inference of recklessness.'" *Id.* (quoting *Kalnit v. Eichler*, 264 F.3d 131, 143 (2d Cir. 2001)). "If no motive or opportunity (other than a generalized business motive) is shown, the circumstantial evidence of conscious misbehavior 'must be correspondingly greater' and show 'highly unreasonable' behavior or that which evinces 'an extreme departure from the standards of ordinary care.'" *Arkansas Public Employees Retirement System v. Bristol-Myers Squibb Co.*, --- F.4th ---, 2022 WL 727149, at *8 (2d Cir. Mar. 11, 2022) (quoting *Kalnit*, 264 F.3d at 142).

The Complaint does not plead facts showing that Defendants knew or should have known they were misrepresenting material facts, "much for the same reasons it fails to plead falsity." *Aratana*, 315 F. Supp. 3d at 765. Plaintiffs' allegations of conscious misbehavior or recklessness hinge on the facts that "Defendants had knowledge of the NISS for OCA in May 2020" and "Defendants were aware of the SAEs that resulted in the NISS," and therefore that the failure to disclose those demonstrates scienter. Dkt. No. 70 at 25–27.

To the extent that Plaintiffs' scienter allegations are grounded in Defendants' alleged omissions, "[b]ecause, as discussed earlier, this case does not present facts indicating a clear duty to disclose, [plaintiffs'] scienter allegations do not provide *strong* evidence of conscious misbehavior or recklessness." *Kalnit*, 264 F.3d at 144. As the Court held above, there was no duty to disclose the SAEs or the NISS because, under *Matrixx*, they were not material, and additionally because Defendants made no statements that were misleading because of the nondisclosure. Failure to disclose facts that Defendants had no duty to disclose cannot support a strong inference of scienter.

To the extent that Plaintiffs' scienter allegations are grounded in Defendants' alleged affirmative misstatements, with regard to all the statements in and before May 2020, the Complaint does not allege with particularity that Defendants knew either of the SAEs or of the NISS at those times. As such, there is no *strong* inference of scienter in their failure to convey that information. With regard to the June 29, 2020 statements, however, the Complaint does sufficiently plead that Defendants knew about the NISS at the time of those statements. Assuming, therefore, that those statements were affirmatively misleading, and that the misstatements were material, the Complaint does support an inference of scienter as to the June 29, 2020 statements, and those statements therefore are not independently dismissed on scienter grounds.

C. Additional Scienter Allegations

Plaintiffs' additional scienter allegations cannot fill this gap. Plaintiffs argue that because "the development of OCA is the Company's core operation since it is literally Intercept's only purpose," and "Intercept was banking its future on the NASH NDA," this "strengthens the inference that the Individual Defendants were aware of the potential risks precluding FDA approval of the NASH NDA, including potential safety risks raised by long-term use of OCA as

exhibited in PBC patients." Dkt. No. 70 at 29. First, this argument once again relies on the existence of a connection between serious adverse events in PBC patients and the FDA's review of the NASH NDA; the Complaint contains no allegations supporting an inference that such a connection exists. Moreover, "merely stating that [a product] was a 'key product' for the Corporate Defendants . . . without more, is plainly insufficient to raise a strong inference of collective corporate scienter." *Jackson v. Abernathy*, 960 F.3d 94, 99 (2d Cir. 2020); *see also Shemian v. Research In Motion Ltd.*, 2013 WL 1285779, at *18 (S.D.N.Y. Mar. 29, 2013) (holding that "while the [core operations] inference may be considered 'as part of a court's holistic assessment of the scienter allegations,' it is not 'independently sufficient to raise a strong inference of scienter,'" and that "without more to tie the Individual Defendants to specific information contradicting the substance of their statements, [the core operations allegation] too is insufficient to give rise to a strong inference of scienter" (alteration adopted) (quoting *Board of Trustees of the City of Ft. Lauderdale General Employees' Retirement System v. Mechel OAO*, 811 F. Supp. 2d 853, 872 (2d Cir. 2011))).

Plaintiffs also argue that the multiple departures at Intercept—including the departure of Pruzanski after nineteen years as CEO in December 2020; the departure of Intercept's Chief Medical Officer, Jason Campagna, in February 2021; and the departure of Kapadia from his role as CFO in March 2021—"support an inference that Intercept was engaged in a deliberate process of removing individuals responsible for overseeing the development of OCA including for both PBC and NASH, which further supports scienter." Dkt. No. 70 at 29–30. While resignations may "add to a pleading of circumstantial evidence of fraud," they are "not themselves sufficient," and even then are only relevant where they are "highly unusual and suspicious." *Glaser*, 772 F. Supp. 2d at 598 (internal quotation marks omitted) (quoting *In re Scottish Re*

Group Securities Litigation, 524 F. Supp. 2d 370, 394 n.176 (S.D.N.Y. 2007)). Plaintiffs allege no additional facts about these resignations that could support a strong inference that they were highly unusual and suspicious; even if the factual allegations of the Complaint could support an inference that the departures were related to the CRL and the failure of Intercept to obtain expedited approval of OCA for treatment of NASH, that is not itself suspicious. *See Arkansas Public Employees Retirement System*, 2022 WL 727149, at *9 ("And the departure of two high-level employees responsible for the trial, which occurred close in time to the announcement of the trial's failure, may reflect the importance that [the defendant] placed on the study's potential success, but is no reason to doubt the veracity or intent of [the defendant's] disclosures.").

III. Loss Causation

Even assuming that the Complaint adequately pleads falsity and scienter, it still falters on its loss causation allegations. "To plead loss causation, a plaintiff must allege that it purchased securities at an inflated price and that the price dropped once the fraud became known." *In re Delcath Systems, Inc. Securities Litigation*, 36 F. Supp. 3d 320, 336 (S.D.N.Y. 2014) (citing *Acticon AG v. China N.E. Petroleum Holdings Ltd.*, 692 F.3d 34, 40 (2d Cir. 2012)). The Court assumes, for purposes of this motion, that loss causation requires only notice pleading and that Plaintiffs need not plead loss causation with particularity. *See Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 346 (2005) ("We concede that the Federal Rules of Civil Procedure require only 'a short and plain statement of the claim showing that the pleader is entitled to relief.' And we assume, at least for argument's sake, that neither the Rules nor the securities statutes impose any special further requirement in respect to the pleading of proximate causation or economic loss." (internal citation omitted) (quoting Fed. R. Civ. P. 8(a)(2))); *see also In re Henry Schein, Inc. Securities Litigation*, 2019 WL 8638851, at *25 (E.D.N.Y. Sept. 27, 2019) (stating that "the majority of district courts in this Circuit have applied Rule 8's pleading

requirements instead of the heightened pleading standards of Rule 9(b)"); *Sharette v. Credit Suisse Int'l*, 127 F. Supp. 3d 60, 80 (S.D.N.Y. 2015) (holding that "in keeping with the prevailing practice of this District, a short and plain statement that provides the defendant with notice of the loss and its causal connection to the alleged misconduct is therefore sufficient to assert loss causation; pleading the elements with particularity is not required").

The Complaint alleges that the "materially false and/or misleading statements and/or omissions" by Defendants "caused the price of Intercept securities to be artificially inflated," and that "[l]ater, when Defendants' prior misrepresentations and/or omissions were disclosed to the market, the price of Intercept shares fell significantly as the prior artificial price inflation dissipated." FAC ¶ 113. Specifically, the Complaint alleges three stock drops: "The truth regarding Intercept was partially revealed, and/or the concealed risks materialized, on or about: May 22, 2020; June 29, 2020; and October 8, 2020. As a direct result of these partial disclosures, the price of Intercept's stock declined precipitously on heavy trading volume." *Id.* ¶ 114.

The alleged May 22, 2020 and June 29, 2020 corrective disclosures both related to roadblocks to Intercept's NASH NDA application; on May 22, Intercept disclosed that the AdCom meeting had been postponed, and on June 29, Intercept disclosed the FDA's CRL denying the application for accelerated approval. Both of these negative disclosures related specifically to the NASH NDA. Both were followed by stock drops. However, neither disclosure either revealed the allegedly concealed information nor constituted the materialization of a risk concealed by Defendants' nondisclosure of the SAEs and the NISS. The risk that OCA would not be approved for NASH was a function of the Intercept application and the data that supported that application; Intercept did not conceal that risk. *See, e.g.*, Dkt. No. 69-3

(Intercept's September 27, 2019 press release announcing the NASH NDA and stating that the NDA, "*if granted*, would result in an anticipated six-month review period," and that "*if approved*, OCA has the potential to become an essential treatment for people living with advanced fibrosis due to NASH" (emphasis added)); Dkt. No. 69-30 (Intercept's September 30, 2019 10-Q stating "OCA may not be approved for NASH or any other indication beyond PBC," and "we cannot guarantee that . . . OCA will ever be approved for use in additional indicates such as NASH," because "NDAs . . . must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication," and "[o]btaining approval of an NDA . . . is a lengthy, expensive, and uncertain process, and we may not be successful in obtaining approval"). That broad risk that the NASH NDA might not be approved on the merits of its application did materialize, and Intercept's stock dropped in response, but that risk was disclosed. That disclosure would not be sufficient if the NISS and the SAEs had a relationship to the FDA's decision. But there is no well-pled allegation that the NISS and the SAEs had such a relationship. As discussed extensively above, the information related to the SAEs and the NISS related to the use of OCA for PBC. The Complaint does not allege facts to support a plausible inference that the SAEs or the NISS had anything to do with the FDA's decision to delay the AdCom meeting or to issue the CRL. At oral argument, Plaintiffs conceded that they "don't believe that [they] have alleged affirmatively specific facts such as an insider or such as a report from the FDA that would say that the reason [they] are rejecting this new drug application is as a result of the issues that are raised by the NISS." Oral Argument Tr. at 18. The Complaint also fails to plead any facts connecting the SAEs and the NISS in PBC patients taking Ocaliva to the approval prospects for the NASH NDA. As such, the Complaint does not plausibly allege that the information

contained in the May 22 and June 29 negative disclosures constituted the materialization of a risk concealed by the failure to disclose the NISS or the SAEs and for that reason cannot establish loss causation. "To plead successfully that [defendants'] fraud caused their losses, plaintiffs [are] required to allege facts to establish that the [defendants'] misstatements and omissions concealed [a specific risk] that materialized and played some part in diminishing the market value of" the stocks. *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 176–77 (2d Cir. 2005); *see also In re AOL Time Warner, Inc. Securities Litigation*, 503 F. Supp. 2d 666, 676 (S.D.N.Y. 2007) ("In each of the cases in which the Second Circuit has employed a materialization of the risk analysis, it has considered a particular risk that was allegedly concealed by the defendant's actions and which then materialized to cause a market loss."). Here, Plaintiffs allege that Defendants concealed the NISS and the SAEs, that doing so concealed the risk that the FDA would not approve Intercept's accelerated NASH NDA because of the NISS and the SAEs, and that such risk materialized when the FDA in fact did not approve Intercept's accelerated NASH NDA. Even assuming that Plaintiffs have plausibly alleged that Defendants concealed the NISS and the SAEs—and that such concealment is actionable under securities fraud law—Plaintiffs allege no facts from which a plausible inference can be drawn that the existence of the SAEs and the NISS posed a risk to the approval of the NASH NDA, which materialized when FDA first delayed the AdCom and then issued the CRL. "The materialization of risk theory . . . requires a direct connection between the risk that is hidden from investors and the subsequent loss suffered by those investors." *Salvani v. ADVFN PLC*, 50 F. Supp. 3d 459, 475 (S.D.N.Y. 2014). The Complaint here fails to plead any such connection.

The October 8, 2020 price decline did relate more directly to the NISS; the Complaint alleges that on October 9:

> STAT News published an article entitled "FDA investigating whether Intercept Pharma drug is tied to potential liver injury risk." The article revealed that, since May 2020, the FDA was investigating Ocaliva for a potential risk of liver disorder in PBC patients and that the probe will likely span 12 months. It questioned: "Did the FDA's liver safety evaluation of Ocaliva, which began in May, contribute to the agency's decision in June to reject the NASH application?"

FAC ¶ 121. It further alleges that "[t]he price decline on October 8, 2020 was the result of the nature and extent of defendants' wrongful conduct being partially revealed to investors and the market. *Inter alia*, the disclosure on October 8, 2020 revealed that the FDA was evaluating a newly identified safety signal." *Id.* ¶ 123. As set forth in detail above, however, Intercept disclosed the NISS on August 11, 2020 in its quarterly report. Notably, Plaintiffs do not allege that that disclosure resulted in any decrease in Intercept's stock price.

The STAT News article contained no new, concealed information about the NISS, beyond the unsupported speculation regarding whether the NISS investigation impacted the FDA's decision with respect to the NASH NDA. While it is true that a "third party's analysis of a company's already-public financial information [can] contribute new information to the marketplace," *In re Chicago Bridge & Iron Co. N.V. Securities Litigation*, 2020 WL 1329354, at *7 (S.D.N.Y. Mar. 23, 2020), particularly with regard to analysis of complicated financial information that may require interpretation, *see id.*, the allegations about the STAT News article do not reflect that the article contained any "analysis" that contributed new information to the marketplace. It simply described the NISS and speculated about a possible connection between the NISS and the NASH NDA. *See In re Omnicom Group, Inc. Securities Litigation*, 597 F.3d 501, 512 (2d Cir. 2010) (stating that "the conclusory suspicions of accounting professors and the unwinding of the . . . transaction added nothing to the public's knowledge," and that "[a] negative journalistic characterization of previously disclosed facts does not constitute a corrective disclosure of anything but the journalists' opinions"); *Janbay v. Canadian Solar, Inc.*,

2012 WL 1080306, at *16 (S.D.N.Y. Mar. 30, 2012) ("However, the raising of questions and speculation by analysts and commentators does not reveal any 'truth' about an alleged fraud as required by *Dura Pharms, Inc.*" (citing *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 342 (2005))).

* * *

Plaintiffs also bring claims against Pruzanski and Kapadia under Section 20(a) of the Exchange Act. "To state a claim under § 20(a), plaintiffs must adequately allege 'a primary violation by the controlled person.'" *Aratana*, 315 F. Supp. 3d at 766 (quoting *Carpenters Pension Trust Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 236 (2d Cir. 2014)). As set forth above, Plaintiffs have not done so; their Section 20(a) claim must therefore be dismissed. *See, e.g.*, *id.* (citing *In re Lions Gate Entertainment Corp. Securities Litigation*, 165 F. Supp. 3d 1, 12–13 (S.D.N.Y. 2016)).

CONCLUSION

The motion to dismiss is GRANTED without prejudice. If Plaintiffs intend to file an amended complaint, they shall do so by April 20, 2022.

The Clerk of Court is respectfully directed to close Dkt. No. 67.

SO ORDERED.

Dated: March 21, 2022
New York, New York

LEWIS J. LIMAN
United States District Judge