UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PATRICIA A. SHENK, *et al.*,

Plaintiffs,

v.

MALLINCKRODT PLC, *et al.*,

Defendants.

No. 17-cv-00145 (DLF)

MEMORANDUM OPINION

Lead Plaintiff State Teachers Retirement System of Ohio (STRS Ohio) brings this putative securities fraud class action against Mallinckrodt plc and two of its senior officers, Chief Executive Officer Mark Trudeau and Chief Financial Officer Matthew K. Harbaugh,[1] alleging violations of Section 10(b) of the Securities Exchange Act of 1934 (Exchange Act), 15 U.S.C. § 78j(b); Securities and Exchange Commission (SEC) Rule 10b–5, 17 C.F.R. § 240.10b–5; and Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a). Before the Court are the defendants' motions to dismiss the consolidated complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Dkt. 60, 61. For the reasons that follow, the Court will grant in part and deny in part the defendants' motions to dismiss.

[1] The lawsuit also named Executive Vice President and Chief Commercial Officer Hugh O'Neill as a defendant. Defendant O'Neill entered into a tolling agreement with the plaintiffs and was voluntarily dismissed without prejudice on August 30, 2018, pursuant to Rule 41(a) of the Federal Rules of Civil Procedure. *See* Voluntary Dismissal of Def. Hugh O'Neill Without Prejudice, Dkt. 63.

I. BACKGROUND

A. Parties

Lead Plaintiff STRS Ohio brings this putative class action lawsuit on behalf of all those who purchased or otherwise acquired Mallinckrodt common stock during the class period, between July 14, 2014 and November 6, 2017. Mallinckrodt is a specialty pharmaceutical company that develops, manufactures, and distributes branded and generic pharmaceutical products in the United States and other countries worldwide. STRS Ohio claims that class members were damaged as a result of allegedly false or misleading material misstatements and omissions that Mallinckrodt and its senior officers made relating to the drug H.P. Acthar Gel (Acthar).

B. Facts

At this stage, the Court accepts as true the plausible allegations in the Amended Consolidated Class Action Complaint. Dkt. 51 (Compl.). The Court also relies on statements or documents incorporated into the complaint by reference, public disclosure documents filed with the SEC, and documents upon which the plaintiffs relied in bringing this suit. *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).[2]

1. Questcor's Acquisition of Acthar and Synacthen

Acthar is an injected medication used to treat many conditions, including infantile spasms and disorders of the joints, skin, eyes, and respiratory system. Compl. ¶ 5 n.1. Acthar works by

[2] In ruling on the defendants' motions, the Court has considered the memoranda of law filed by defendant Mallinckrodt, Dkt. 60 (Def.'s Br.), and the individual defendants, Dkt. 61 (Indiv.'s Br.); STRS Ohio's opposition, Dkt. 64 (Pls.' Opp'n); Mallinckrodt's reply, Dkt. 66 (Def.'s Reply), and the individual defendants' reply, Dkt. 67 (Indiv.'s Reply). The Court also has considered the declarations and exhibits submitted with those briefs to the extent they contain material appropriate for consideration under Rule 12(b)(6), and the Court has considered the transcript of the parties' November 19, 2018 hearing on the motions, Dkt. 68 (Tr.).

stimulating adrenal gland cells to foster a natural steroid hormone production that reduces inflammation. *Id.* The Food and Drug Administration (FDA) licensed Acthar in 1952 as the only natural therapeutic adrenocorticotropic hormone (ACTH) drug approved for use in the United States. *Id.* ¶ 5.

In 2001, a company called Questcor purchased Acthar for the relatively low price of $100,000, plus modest royalties. *Id.* ¶ 7. Questcor then boosted marketing and sales for Acthar, and Acthar's price rose from $40 per vial in 2001 to $28,000 per vial in 2012. *Id.* ¶ 10. By 2013, Acthar sales accounted for more than 95% of Questcor's total revenues. *Id.*

Before 2013, a European company called Novartis owned a synthetic ACTH drug, called Synacthen, which was the only other ACTH drug that could potentially compete with Acthar in the United States. *Id.* ¶ 13–14. Novartis sought to license the rights to sell Synacthen in the United States, but Questcor outbid three other companies (including Retrophin, a competing biopharmaceutical company) and secured the rights to develop, manufacture, and sell Synacthen in the United States and elsewhere in June 2013. *Id.* ¶ 17–19.

In a June 2013 press release, Questcor's Chief Scientific Officer stated that Questcor intended to seek FDA approval for Synacthen to develop it in the United States for conditions that Acthar did not treat and for conditions "where Synacthen would potentially provide a clinical benefit over Acthar." *Id.* ¶ 19, 67. Then in January 2014, Retrophin filed a lawsuit alleging that Questcor's Synacthen acquisition violated U.S. antitrust laws. *Id.* ¶¶ 93, 153. Questcor disclosed the existence of the Retrophin litigation on February 26, 2014, in its 2013 10-K. *See* Def.'s Br. at 15; *see also id.* Ex. 5 at 28. In spring 2014, Questcor learned that the sole worldwide manufacturer of Synacthen would cease manufacturing it in April 2016. Compl. ¶ 106.

2. Mallinckrodt's Acquisition of Questcor

On April 7, 2014, Mallinckrodt announced its acquisition of Questcor, which gave Mallinckrodt ownership of Questcor's licenses for both Acthar and Synacthen and thus a monopoly ACTH position in the U.S. market. *Id.* ¶¶ 11–12, 79. Two months later, on June 11, 2014, the Federal Trade Commission (FTC) sent Questcor a subpoena and Civil Investigative Demand, which revealed to Mallinckrodt that the FTC was investigating whether Questcor's Synacthen acquisition violated U.S. antitrust laws. *Id.* ¶¶ 100, 102–104.

On July 14, 2014, the beginning of the class period, Mallinckrodt and Questcor filed a joint proxy statement with the SEC in connection with the companies' shareholder votes to approve the merger. *Id.* ¶ 100. The proxy statement claimed that Mallinckrodt had consulted "legal advisors" and had conducted a due diligence investigation of Questcor, including "in-depth reviews of" both "legal" and "regulatory" matters. *Id.* ¶ 103. However, neither company disclosed the existence of the FTC investigation or the subpoena and investigative demand sent to Questcor prior to the consummation of the merger. *Id.* ¶¶ 100, 105. Further, neither company disclosed that the sole worldwide manufacturer of Synacthen had informed Questcor in the spring of 2014 that it would cease manufacturing the drug in 2016. *Id.* ¶ 109. Mallinckrodt's acquisition of Questcor was completed on August 14, 2014. *Id.* ¶ 12.

Between June 11, 2014 and November 25, 2014, Mallinckrodt filed a quarterly Form 10-Q report and nine separate 8-K reports with the SEC. *Id.* ¶ 105. Mallinckrodt first disclosed the existence of the FTC investigation in its 2014 10-K, filed on November 25, 2014, *id.* ¶ 116, and it continued to disclose the fact of the ongoing investigation on its Form 10-K for both the 2015 and 2016 fiscal years, *id.* ¶ 117. The plaintiffs do not allege that Mallinckrodt's stock price

declined immediately following the November 25, 2014 disclosure. Def.'s Br. at 45; *see* Compl. ¶ 201–08.

3. Acthar's Medicare and Medicaid Exposure

One risk factor for the proposed merger, as identified in the 2014 joint proxy statement, was the percentage of Acthar sales reimbursed by Medicare and Medicaid rather than by private insurers. *Id.* ¶ 127. Investors understood that, in the pharmaceuticals industry, a high level of dependency on Medicare and Medicaid reimbursements would expose significant revenue streams to federal policy shifts, including those targeting pharmaceutical prices. *Id.* ¶ 24.

On October 26, 2015, during a guidance call with investors, defendant Trudeau, Mallinckrodt's CEO, was asked about Acthar's "exposure to Medicare." *Id.* ¶ 128. In response, Trudeau stated that "the combined proportion of [Mallinckrodt's] business that goes through Medicare and Medicaid combined [is] about a quarter of our business, roughly" and that "Acthar is maybe a little higher than that." *Id.* However, data released on November 14, 2016 by the Centers for Medicare and Medicaid Services (CMS) and repeated in an online investment newsletter called a Citron Research Report (the Citron Report) published on November 16, 2016, purported to show that the percentage of Mallinckrodt's Acthar sales reimbursed by Medicare and Medicaid was over 45% in 2013, over 60% in 2014, and over 61% in 2015. *Id.* ¶ 129.

On November 17, 2016, the day after the Citron Report was released, Mallinckrodt's investor-relations executives presented slides at a healthcare conference. *Id.* ¶ 142. According to the complaint, the presentation did not "contradict[] the percentages of Acthar revenues paid through Medicare and Medicaid" for the years discussed in the Citron Report. *Id.* Shortly after the presentation, a Mallinckrodt senior vice president stated that Acthar's "core" 2016 Medicare exposure was "somewhere in the mid-40s percent range," that Acthar's 2016 Medicaid exposure

was "probably in the mid-single digit range," and that there were "[s]imilar numbers last year." *Id.* ¶ 143. The same senior vice president also stated that Acthar's Medicare exposure two years earlier was "probably in the mid-30s . . . with a mid-single digit, maybe a little bit higher kind of Medicaid impact." *Id.* From November 15, 2016 to November 17, 2016, Mallinckrodt's stock price fell 18.4%. *Id.* ¶ 205.

4. The Filing of the FTC complaint

Meanwhile, Mallinckrodt settled Retrophin's antitrust suit in June 2015, *id.* ¶ 93, but the FTC's investigation of Mallinckrodt's potential antitrust violations continued. As noted, Questcor originally indicated that it intended to seek FDA approval to use Synacthen to treat conditions Acthar did not treat and at least some of the same conditions that Acthar treated to the extent Synacthen offered a clinical benefit over Acthar. *Id.* ¶ 19. But the plaintiffs allege that, following the merger, Mallinckrodt only sought FDA approval to use Synacthen to treat a single condition, Duchen Muscular Dystrophy (DMD), which Acthar does not treat. *Id.* ¶¶ 84–86. The plaintiffs also allege that statements made by a confidential witness, a former Mallinckrodt vice president, confirm that Mallinckrodt consciously decided not to develop Synacthen for an economic, rather than a medical, reason: to avoid competition with Acthar. *See id.* ¶¶ 88–92.

On November 29, 2016, Mallinckrodt filed its 2016 10-K, which like its 2015 10-K disclosed the fact of the ongoing FTC investigation but stated that Mallinckrodt was "not aware of any existing or pending litigation in connection with" the investigation. *Id.* ¶ 117. Mallinckrodt also disclosed in its 2016 10-K that the ultimate resolution of the investigation "could have a material adverse effect on its financial condition, results of operations, and cash flows." *Id.*

On January 18, 2017, fifty days after Mallinckrodt's 2016 10-K was filed, the FTC filed a complaint and consent decree in the United States District Court for the District of Columbia. *Id.* ¶¶ 118, 126. The FTC alleged that Questcor's acquisition of the rights to develop Synacthen, a synthetic ACTH drug, amounted to illegal monopolization. *Id.* ¶ 81. On the same day, Mallinckrodt entered into a settlement agreement with the FTC. *Id.* ¶¶ 81, 153. The settlement required Mallinckrodt to pay a $100 million fine and to sub-license certain U.S. development rights to Synacthen for two conditions treated by Acthar, Infantile Spasms and Nephrotic Syndrome. *Id.* ¶ 33. The plaintiffs allege that "it is hard to imagine that [Mallinckrodt] was not in negotiations with the FTC for at least several months" before the settlement, *id.* ¶ 118, and that based on FTC practice, the defendants "must have been aware" that the FTC was planning to file the complaint and highly-negotiated settlement well in advance of the filing of Mallinckrodt's 2016 10-K, *id.* ¶¶ 119–126. On the day the FTC settlement was announced, Mallinckrodt's stock price fell 5.85%. *Id.* ¶ 34.

5. 2017 Statements About Acthar's Prospects

Throughout 2017, the defendants made a series of statements regarding the long-term prospects for Acthar sales. On January 19, 2017, the day after the FTC settlement announcement, Mallinckrodt held a "Business Update Call" with analysts. *Id.* ¶ 153. On the call, Trudeau stated that Acthar was "an exceptionally durable asset" and that it would "be able to consistently drive mid-single-digit to low double-digit growth based predominantly on volume." *Id.* Mallinckrodt also addressed the FTC settlement as "another step forward in [Mallinckrodt's] overall overhang de-risking process" stemming from the Questcor acquisition. *Id.*

On February 7, 2017, Mallinckrodt reported results for the end of 2016 and provided guidance for 2017, including earnings per share projections. *Id.* ¶ 154. On an earnings call the same day, Trudeau reiterated Mallinckrodt's expectations about future growth based on volume increases, and he addressed an analyst question about the payer mix for Acthar as between commercial and public payer plans. *Id.* ¶ 156. He stated that Mallinckrodt was seeing "good growth across the payer mix" for Acthar, including "very good growth in both commercial as well as public payers." *Id.*

On May 8, 2017, Mallinckrodt released its results for the first quarter of 2017. *Id.* ¶ 157. In the press release, Trudeau was quoted commenting on Acthar sales. He stated that Mallinckrodt was continuing "to see strengthening in Acthar formulary positions and access for appropriate patients in both the commercial and public environments" and that Mallinckrodt was continuing to see "relaxation or removal of previous formulary restrictions." *Id.* The plaintiffs allege that Trudeau's statements about strengthened formulary positions conveyed to the market that Acthar was included in more formularies of medications approved by insurers and that insurers had expanded the circumstances for which they would approve and provide reimbursement for Acthar. *Id.* ¶ 161 n.28.

During an earnings call the same day, Trudeau reiterated statements about strengthened formulary positions, access to Acthar, and the relaxation or removal of formulary restrictions. *Id.* ¶ 161. Trudeau further stated that Acthar was achieving 60% "commercial lives under contract" (a statement that would indicate an increase from prior years in Acthar's commercial payer positioning) giving Mallinckrodt "good confidence" in its growth projections. *Id.* ¶ 158. Harbaugh, Mallinckrodt's Chief Financial Officer, added that a rebating strategy used by Mallinckrodt for Acthar was also "fully considered in the guidance" provided to investors. *Id.*

On May 19, June 6, and June 22, 2017, Mallinckrodt issued a series of press releases in response to reports issued by short-sellers. *Id.* ¶ 159. Those press releases stated that Acthar's efficacy was "strongly supported by evidence," that the company had expanded "commercial lives under contract," and that the "majority of payers have an established pathway for the use of" Acthar for "conditions covered by the FDA-approved label and for whom the product's extensive existing data and clinical experience support [Acthar's] use as a proven therapy." *Id.*

On August 8, 2017, the company announced second quarter results for 2017 in a press release and held an analyst call where it reported increased Acthar net sales from the same quarter in 2016. *Id.* ¶ 160. The company also reiterated its prior earnings per share projections, discussed projected future growth across the payer mix, made claims about strengthening formulary positions, and forecasted volume-driven growth. *Id.* ¶ 161.

Finally, on November 7, 2017, Mallinckrodt reported that net sales for Acthar in the third quarter of 2017 had declined from the third quarter of 2016. *Id.* ¶ 168. On an earnings call that day, Trudeau stated that sales had slowed due to an additional selling week in 2016 "and a volume decline." *Id.* ¶ 169. He also discussed an increasing number of prescriptions going unfilled and continued payer pressures as causes of the declining sales. *Id.* On the day Mallinckrodt disclosed its declining sales, its stock price dropped 35.5%. *Id.* ¶ 189.

C. Procedural History

Plaintiff Patricia Shenk filed the initial complaint on January 23, 2017. Dkt. 1. Plaintiff STRS Ohio then moved the Court to consolidate this case with multiple similar lawsuits, pursuant to Rule 42(a) of the Federal Rules of Civil Procedure, and it moved to appoint STRS Ohio as lead plaintiff. Dkt. 16. The Court granted STRS Ohio's motion on March 9, 2018, Dkt. 45, and on May 18, 2019, STRS Ohio filed the Amended Consolidated Class Action Complaint,

Dkt. 51. On July 17, 2018, the defendants filed their motions to dismiss the consolidated complaint, Dkt. 60–61, which was fully briefed on October 1, 2018, Dkt. 64, 66–67. The Court held a motions hearing on November 19, 2018. Dkt. 68.

II. LEGAL STANDARDS

A. Motions to Dismiss

To survive a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "Although the court need not accept the plaintiff's legal conclusions, the court must assume the truth of all well-pleaded factual allegations in the complaint and draw all reasonable inferences from those allegations in the plaintiff's favor." *In re Harman Int'l Indus., Inc. Sec. Litig.*, 791 F.3d 90, 99–100 (D.C. Cir. 2015). Nonetheless, "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555 (citations omitted).

B. Securities Fraud

Securities fraud claims are subject to heightened pleading standards under Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u–4(b). To satisfy Rule 9(b), the plaintiffs must "state with particularity the circumstances constituting fraud . . ." Fed. R. Civ. P. 9(b). For alleged misleading statements and omissions, the PSLRA requires the plaintiffs to "specify each statement alleged to have been misleading, the

reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . [to] state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1).

As to the element of scienter, or the defendant's mental state, the PSLRA demands that the plaintiffs "state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." *Id.* § 78u–4(b)(2)(A) (emphasis added). A "strong" inference is one that is "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). Thus, "[i]n determining whether this inference can be reasonably drawn, courts must consider both the inferences urged by the plaintiff and any competing inferences rationally drawn from all the facts alleged, taken collectively." *ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009) (citing *Tellabs*, 551 U.S. at 314, 323).

III. DISCUSSION

The plaintiffs allege that Mallinckrodt and the individual defendants made a variety of material misstatements and omissions during the class period. Count I of the amended consolidated complaint alleges that the defendants violated Section 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b–5, 17 C.F.R. § 240.10b–5. Compl. ¶ 225. Count II alleges that the individual defendants, Trudeau and Harbaugh, the Chief Executive Officer and Chief Financial Officer, respectively, are subject to "control person" liability for securities fraud under Section 20(a) of the Securities Exchange Act, 15 U.S.C. § 78t(a). *Id.* ¶¶ 237–39. The defendants move to dismiss both counts of the consolidated complaint. For the

reasons stated below, the Court will grant in part and deny in part the defendants' motions to dismiss.

A. The Section 10(b) and Rule 10b–5 Claim

To state a claim for securities fraud under Section 10(b) of the Exchange Act and SEC Rule 10b–5, a plaintiff must allege: "(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." *Halliburton Co. v. Erica P. John Fund, Inc. (Halliburton II)*, 573 U.S. 258, 267 (2014) (quoting *Amgen Inc. v. Connecticut Retirement Plans and Trust Funds*, 568 U.S. 455, 460–61 (2013)). In their motions, the defendants argue that the plaintiffs fail to allege (1) actionable material misstatements or omissions, (2) scienter, and (3) loss causation (for some claims).

As explained below, the Court concludes that the plaintiffs' have successfully stated a claim under Section 10(b) and Rule 10b–5 with respect to (1) the defendants' alleged failure to disclose the fact of an impending settlement with the FTC in Mallinckrodt's 2016 10-K; (2) Trudeau's alleged misstatement regarding Acthar's exposure to Medicare and Medicaid in October 2015; and (3) the defendants' alleged misstatements and omissions in 2017 regarding the long-term prospects for Acthar's sales as far as they relate to statements about (a) Acthar's growth across the payer mix, (b) strengthened formulary positions and the removal or relaxation of formulary restrictions, and (c) specific growth projections. However, the Court will grant the defendants' motions and dismiss the plaintiffs' claims with respect to (1) the defendants' alleged failure to disclose the FTC subpoena and investigative demand in the 2014 joint proxy for failure to plead loss causation; (2) the defendants' alleged failure to disclose that the sole worldwide

manufacturer of Synacthen would cease manufacturing it in 2016 for failure to plead materiality, scienter, and loss causation; (3) the defendants' statements and omissions regarding its competitive position pertaining to Acthar—in particular, the defendants' alleged failure to disclose an unlawful antitrust scheme and the defendants' alleged misstatements about Acthar's commercial durability—for failure to plead materiality and scienter; and (4) the defendants' alleged misstatements and omissions in 2017 regarding the strength of the scientific evidence supporting Acthar for failure to plead materiality, scienter, and loss causation.

1. Material Misstatements and Omissions

To establish a material misstatement or omission, a plaintiff must show that a statement was both misleading and material. The statement "must be 'material' in the sense that it would have 'been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'" *In re Harman*, 791 F.3d at 108 (quoting *Halliburton II*, 573 U.S. at 278). "[M]ateriality depends on the significance the reasonable investor would place on the withheld or misrepresented information." *Basic Inc. v. Levinson*, 485 U.S. 224, 240 (1988).

Materiality is a mixed question of law and fact that "involves a delicate assessment of the inferences a reasonable shareholder would draw from a . . . statement and a projection of the significance of these inferences to the hypothetical reasonable shareholder." *Berg v. First Am. Bankshares, Inc.*, 796 F.2d 489, 495 (D.C. Cir. 1986). "Only if the alleged misrepresentation[] or omission[] [is] so clearly unimportant to an investment decision that reasonable minds cannot differ should the issue of materiality appropriately be resolved as a matter of law by . . . a motion to dismiss." *Id.* (citing *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976)). The D.C. Circuit has explained that corporate "puffery," or a "generalized statement[] of optimism that [is] not capable of objective verification," is "immaterial and inactionable" because it is "too

squishy, too untethered to anything measurable, to communicate anything that a reasonable person would deem important to a securities investment decision." *In re Harman*, 791 F.3d at 109 (citations omitted).

"[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor: The inquiry (like the one into materiality) is objective." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015) (citation omitted). Thus, because "[a] reasonable person understands, and takes into account, the difference . . . between a statement of fact and one of opinion," "a statement of opinion is not misleading just because external facts show the opinion to be incorrect." *Id.* at 1328. Material statements of opinion may be actionable misstatements where the speaker did not hold the opinion asserted at the time he asserted it, or when the opinion expressed cites a "supporting fact" that is itself untrue. *Id.* at 1327. If a reasonable investor would "understand an opinion statement to convey facts about how the speaker has formed the opinion," "[a]nd if the real facts are otherwise, but not provided, the opinion statement will mislead its audience." *Id.* at 1328; *see also Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1277 (D.C. Cir. 1994) (reasoning that forward-looking statements such as opinions or projections are "misleading for the purposes of the securities laws if they were issued without good faith or lacked a reasonable basis when made").

To establish a material omission, a plaintiff must establish a duty to disclose the relevant material fact. In other words, absent a duty to disclose, a company is not required to disclose even "information that a reasonable investor might consider material." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 (2011); *see also id.* at 44 (the securities laws do not create a blanket "duty to disclose any and all material information"); *Basic*, 485 U.S. at 239, n.17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b–5."). When there is no

allegation of corporate insider trading or a statute or regulation that would mandate disclosure, a duty to disclose arises when the disclosure of the omitted fact is "necessary to make statements made, in the light of the circumstances under which they were made, not misleading." *Matrixx*, 563 U.S. at 44 (alteration adopted and internal quotation marks and citations omitted); *see also In re Time Warner Inc. Securities Litigation*, 9 F.3d 259, 268 (2d Cir. 1993) (noting that "a duty to disclose arises when disclosure is necessary to make prior statements not misleading") (citation omitted).

The plaintiffs argue that the defendants made a series of material misstatements and omissions that can be grouped into three categories: (1) statements about Acthar's competitive environment, (2) statements about Acthar's Medicare and Medicaid exposure, and (3) statements about Acthar's 2017 sales prospects. Pls.' Opp'n at 1–2. The Court will address each category in turn.

a. Statements and Omissions Regarding Acthar's Competitive Environment

The plaintiffs argue that the defendants made material misstatements and omissions regarding Acthar's competitive environment by (1) failing to disclose the fact of the FTC investigation in the 2014 joint proxy statement, Pls.' Opp'n at 4; (2) failing to disclose that the sole worldwide manufacturer of Synacthen would cease manufacturing the drug in 2016, Pls.' Opp'n at 5; (3) misstating Mallinckrodt's competitive positioning pertaining to Acthar, Pls.' Opp'n at 5–6; and (4) failing to disclose the impending FTC complaint and consent decree in Mallinckrodt's 2016 10-K, Pls.' Opp'n at 6–7.

Because the Court concludes, *infra*, that the plaintiffs have not pleaded facts sufficient to establish loss causation with respect to the defendants' alleged (1) failure to disclose the fact of the FTC investigation in the 2014 joint proxy, the Court need not decide whether the plaintiffs

have met their burden with respect to materiality on that claim. As to the remaining alleged misstatements and omissions relating to Acthar's competitive environment, the plaintiffs have failed to meet their burden on materiality with respect to both the defendants' (2) alleged failure to disclose that the sole worldwide manufacturer of Synacthen would cease manufacturing the drug in 2016 and (3) alleged misstatement of Mallinckrodt's competitive positioning pertaining to Acthar. However, the plaintiffs have met their burden on materiality with respect to the defendants' (4) alleged failure to disclose in Mallinckrodt's 2016 10-K the impending filing of the FTC complaint, settlement, and consent decree.

i. The failure to disclose that the sole worldwide manufacturer of Synacthen would cease manufacturing the drug in 2016

The plaintiffs argue that it was materially misleading for Mallinckrodt to fail to disclose in the 2014 joint proxy statement that the sole worldwide manufacturer of the competing drug Synacthen would cease manufacturing the drug in 2016 due to the planned decommissioning of the sole production site. Compl. ¶ 106. The plaintiffs acknowledge that the defendants disclosed in the joint proxy statement various risk factors related to the development of Synacthen, such as risks surrounding Mallinckrodt's ability to maintain "important business relationships" and its "efforts to develop and obtain FDA approval of Synacthen." *Id.* ¶ 100. Nevertheless, the plaintiffs contend that "merely report[ing] [these] as a risk in the joint proxy statement" was not enough. Pls.' Opp'n at 5; *see also* Compl. at ¶ 109.

The Court is unconvinced that the defendants' failure to disclose a drug manufacturer's future plans to close its production facility was a materially misleading omission. A corporation need only disclose a fact "if there is a substantial likelihood that disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information available." *In re Time Warner*, 9 F.3d at 267–68 (internal quotation marks and

citation omitted). But "a corporation is not required to disclose a fact merely because a reasonable investor would very much like to know that fact." *Id.* at 267. And even the disclosure of a risk factor does "not trigger a generalized duty requiring defendants to disclose the entire corpus of their knowledge." *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 366 (2d Cir. 2010) (citation omitted).

Here, the defendants disclosed as a risk factor the ability to maintain important business relationships, which presumably included relationships with drug manufacturers. Disclosing the manufacturer's plans to close its facility in two years would not have significantly altered the total mix of information available to a reasonable investor because a reasonable investor could have assumed that, within two years' time, Mallinckrodt would have been able to identify a different manufacturer for the drug. This alleged omission was "so clearly unimportant to an investment decision that reasonable minds cannot differ." *Berg*, 796 F.2d at 495. Moreover, the plaintiffs fail to explain with particularity why the defendants' knowledge of a potential, yet uncertain, decommissioning triggered a duty to disclose something more than the risks they disclosed in the joint proxy. Thus, even if the alleged omission could be understood to be material, the plaintiffs have failed to satisfy their burden under the PLSRA to "demonstrate with specificity why and how" it was misleading. *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 236 (2d Cir. 2014) (quoting *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004)). The Court will therefore dismiss the plaintiffs' claim that the defendants materially misled investors by not disclosing the manufacturer's plans in the 2014 proxy statement.

ii. Misstatements about Mallinckrodt's competitive positioning pertaining to Acthar

The plaintiffs argue that the defendants made a series of false and materially misleading statements about Mallinckrodt's competitive positioning pertaining to Acthar in Mallinckrodt's 2014, 2015, and 2016 10-Ks, and in earnings calls where Trudeau addressed analysts and investors. Compl. ¶¶ 110–15. In particular, the plaintiffs allege that the defendants' various statements about Acthar's competitive environment, namely that Acthar had "limited direct competition" and "commercial durability," were materially false and misleading because Acthar's competitive advantages were due to Mallinckrodt's anticompetitive practices. *Id.* ¶ 115.

The Court disagrees. Even assuming that the complaint adequately alleges an unlawful anticompetitive scheme (which is questionable), the plaintiffs fail to allege that the challenged statements were misleading absent the disclosure of the purported scheme. *First*, the consolidated complaint lacks factual allegations that support the theory that in November 2014, Synacthen was, or plausibly could have become, a direct competitor to Acthar but for Mallinckrodt's alleged anticompetitive conduct. At the time that the 2014 10-K was filed, Acthar did in fact have limited direct competition because of its unique nature as a naturally-derived product. Because Synacthen had not been approved by the FDA for use in the United States at that time, it was not in "direct competition" with Acthar. *Id.* ¶ 110. Indeed, even the FTC complaint, which was filed more than two years later and cited in the amended consolidated complaint, referred to Synacthen as a "nascent" competitive threat to Acthar and recognized "the significant uncertainty that Synacthen, a preclinical drug, would be approved by the FDA." Def.'s Br. at Ex. 17 ¶ 34; *see also* Compl. ¶ 32. In addition, at the time its 2014 10-K was published, Mallinckrodt had owned both Acthar and Synacthen for only three months. *See*

Compl. ¶ 60 (stating that "[i]n August 2014, Mallinckrodt acquired Questcor"). And the complaint alleges no facts supporting an inference that Mallinckrodt could have secured Synacthen's FDA approval in that short period of time.

Second, none of the ten risk factors noted in the defendants' 2014, 2015, and 2016 10-Ks, *id.* ¶ 110, were misleading for failing to indicate that Acthar's commercial viability actually depended on "Mallinckrodt's anticompetitive practices in preventing Synacthen from reaching the U.S. market," *id.* ¶ 115. One of those disclosed factors identified Mallinckrodt's "ability to implement and maintain pricing actions and continue to maintain or increase market demand for these products," and another identified "whether the Federal Trade Commission ('FTC') . . . seek[s] to challenge and [is] successful in challenging . . . our sales and marketing practices." *Id.* ¶ 110. Investors were aware that Mallinckrodt owned both Acthar and the Synacthen, and the defendants' disclosures were sufficient to put investors on notice of the risk that the FTC could seek to challenge alleged anticompetitive conduct related to Mallinckrodt's sales and marketing of Acthar. In other words, a further disclosure would not "have been viewed by the reasonable investor as having significantly altered the 'total mix' of information available." *In re Time Warner*, 9 F.3d at 267–68 (citation omitted).

Third, the defendants were not required to accuse themselves of wrongdoing or employ pejorative adjectives to describe their conduct. Rather, "[s]ince the use of a particular pejorative adjective will not alter the total mix of information available to the investing public, such statements are immaterial as a matter of law and cannot serve as the basis of a 10b–5 action under any theory." *Kowal*, 16 F.3d at 1277 (citations omitted). "Disclosure is not a rite of confession," meaning that companies "do not have a duty to disclose uncharged, unadjudicated wrongdoing." *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 184

(2d Cir. 2014) (citations and internal quotation marks omitted). The market was aware that Mallinckrodt owned both Acthar and Synacthen, and Mallinckrodt disclosed the risk of government enforcement affecting its business strategy, and continued to do so thereafter. There is no allegation that the FTC challenged Mallinckrodt's decision not to compete the two drugs; the complaint only addressed Questcor's *acquisition* of Synacthen. Def.'s Br. at Ex. 17 ¶¶ 33–52.

Fourth, the plaintiffs allege that Mallinckrodt's decision not to compete the two drugs corroborated the alleged anticompetitive scheme because it was a reversal from Questcor's position when Questcor owned Synacthen. Compl. ¶ 87. In June 2013, Questcor's Chief Scientific Officer stated that it was committed to developing Synacthen for conditions that Acthar treats where Synacthen "would potentially provide a clinical benefit over Acthar." *Id.* ¶ 67. Even so, the plaintiffs do not allege facts showing that Mallinckrodt knew or should have known of indications where Synacthen would potentially provide a clinical benefit over Acthar and yet decided not to compete the drugs. Thus, the plaintiffs have not established a reversal of position on the part of Mallinckrodt that could provide grounds for pleading a material misstatement or omission.

Finally, the plaintiffs claim that Trudeau's statements on the October 6, 2015 investor call were misleading because Trudeau did not disclose that Acthar's lack of competition resulted from Mallinckrodt's unlawful monopolization of the market for ACTH medications. *See* Pls.' Opp'n at 51 (arguing that these statements failed to acknowledge that Mallinckrodt's "exclusive license to develop Synacthen in the U.S. market forestalled . . . competition from emerging"). But these statements were not materially misleading for many of the same reasons that the alleged misstatements in the 2014, 2015, and 2016 10-Ks were not misleading. During the

October 2015 call, Trudeau discussed Acthar's "significant durability and great potential for long-term volume growth" and stated, among other things, that "[b]ased on what we know about the unique characteristics of Acthar itself, the complicated regulatory environment for complex, naturally-derived products, and the lack of successful market precedent, we continue to believe that the path to market for a direct competitor to Acthar is uncertain and likely to be potentially long." Compl. ¶ 112. When asked to comment on Acthar's competition, Trudeau added that "the very nature of Acthar being a naturally derived complex mixture of organic components makes it I think particularly difficult to develop a direct competitor," *id.* ¶ 113, and "it's a very complex environment with tremendous barriers and lots of unknown information," *id.* ¶ 114. At the time Trudeau made these statements, Acthar was in fact a "unique" naturally-derived ACTH medication, and the synthetic drug Synacthen was not yet a direct competitor to Acthar.

Further, Trudeau was not obligated to acknowledge that its Synacthen license ownership created anticompetitive effects in the U.S. market because investors were already aware that Mallinckrodt owned both Acthar and Synacthen, and Mallinckrodt had previously disclosed the underlying facts and risks regarding potential antitrust enforcement. In addition, the statements indicating Trudeau's "belief" or what he "th[ought]" to be the case were statements of opinion, which are only "misleading for the purposes of the securities laws if they were issued without good faith or lacked a reasonable basis when made." *Kowal*, 16 F.3d at 1277 (citations omitted). The complaint does not adequately allege that Trudeau made these statements without good faith or without a reasonable basis. Indeed, in context, Trudeau's statements focused on the organic nature of Acthar, as demonstrated by his comments about "the complicated regulatory environment for complex, naturally-derived products" and "the very nature of Acthar being a naturally derived complex mixture of organic components." Compl. ¶ 113. The status of a

synthetic drug like Synacthen would have had no bearing on the veracity of those statements. And as noted, Trudeau's statements were based on facts about the competitive environment for Acthar that were true at the time the statements were made.

For these reasons, the complaint fails to adequately allege facts sufficient to establish that the statements that the defendants made in Mallinckrodt's SEC filings and investor calls were materially misleading to the extent that they involved statements about Acthar's competitive environment and commercial durability. Accordingly, the plaintiffs' claims with respect to these statements will be dismissed for failure to state a claim.

iii. The failure to disclose the impending FTC complaint and consent decree in Mallinckrodt's 2016 10-K

The plaintiffs also argue that Mallinckrodt's November 29, 2016 10-K was materially false and misleading with regard to the ongoing FTC investigation because it omitted the fact of an impending complaint and consent decree (along with an accompanying settlement and fine) that was filed by the FTC fifty days after the 2016 10-K was issued. *Id.* ¶¶ 117–18, 126.

Although the securities laws do not impose a roving obligation to predict all possible contingencies, *In re Ford Motor Co. Sec. Litig.*, 184 F. Supp. 2d 626, 633 (E.D. Mich. 2001), *aff'd*, 381 F.3d 563 (6th Cir. 2004), a duty to disclose can arise where a corporate statement "would otherwise be inaccurate, incomplete, or misleading" absent further disclosure. *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 101 (2d Cir. 2015) (internal quotations marks and citations omitted). In other words, when a corporation decides to speak on a subject, it has a "duty to be both accurate and complete." *Caiola v. Citibank*, 295 F.3d 312, 331 (2d Cir. 2002); *see also In re Time Warner*, 9 F.3d at 268 ("[The] duty to disclose arises when disclosure is necessary to make prior statements not misleading."); *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 160 (S.D.N.Y. 2008) (reasoning that, when a corporation elects to speak on

a subject, "Rule 10b–5 mandates that its speech must be truthful, accurate, and complete") (citations omitted). When an alleged omission involves impending litigation in particular, "there is no requirement to make disclosures predicting such litigation" unless "the litigation [is] substantially certain to occur during the relevant period." *In re Marsh & Mclennan Companies, Inc. Sec. Litig.*, 501 F. Supp. 2d 452, 471 (S.D.N.Y. 2006) (internal quotation marks and citations omitted).

Here, Mallinckrodt's 2014 10-K disclosed that the FTC had issued a subpoena and civil investigative demand, and it identified government litigation challenges as a risk factor in maintaining and increasing its net sales. Compl. ¶¶ 110, 116. Mallinckrodt's 2015 and 2016 10-K filings repeated this disclosure and added that Mallinckrodt was not aware of "existing or pending litigation" in connection with the FTC's investigation but that resolution of the investigation "could have a material adverse effect on [Mallinckrodt's] financial condition, results of operations, and cash flows." *Id.* ¶ 117. Aside from these disclosures, the defendants revealed no additional information about the FTC investigation to the public.

At the motion to dismiss stage, a court must "draw all reasonable inferences from [well-pleaded] allegations in the plaintiff's favor." *In re Harmon*, 791 F.3d at 99–100. The complaint alleges that the defendants were aware "well in advance" of the January 18, 2017 announcement that a complaint and consent decree were impending. Compl. ¶ 125; *see also id.* ¶ 118 (alleging that "the FTC would have informed Mallinckrodt that it was pursuing the investigations into a more serious realm" by November 29, 2016); *id.* (alleging that "it is hard to imagine" that the defendants had not been in negotiations about the details of the FTC settlement terms months in advance). To support their claim that the defendants had knowledge that the litigation and

settlement was substantially certain to occur, the plaintiffs rely heavily on the FTC's standard practices as set forth in the FTC's Operating Manual (FOM). *Id.* ¶ 119–25.

The FOM is not "a directive to the staff from the Commission," but it does advise agency staff "to follow the procedures outlined in the [Manual] unless circumstances warrant modification." FOM Chapter 1, § .1.1. As explained in the FOM, the FTC must first "develop sufficient facts" with respect to the details of the allegations, charges, and proposed relief. FOM Chapter Six, § .3.1. And the settlement process itself involves several layers of internal FTC review. For example, when negotiating a settlement, the FTC staff consults with various levels of FTC directors. *Id.* §§ .3.2, .9.1. Following the approval of a settlement, the materials "shall be forwarded" to various senior government officials within 30 calendar days and further "action on staff recommendation shall be completed within 35 calendar days." *Id.* § .9.1.

The defendants point out that the FOM contemplates that the settlement process take *no more* than 65 days, not that it cannot take less than 65 days. Def.'s Reply at 11. They further note, citing a single *Washington Post* article neither cited, referenced, nor relied upon in the complaint, the "well-documented effort by agencies to speed up proceedings prior to the beginning of the Trump administration." Def.'s Reply at 11 n.9. Finally, the defendants assert that the mere possibility of litigation cannot be "pending" litigation. Def.'s Br. at 20–21; *Swartz v. Meyers*, 204 F.3d 417, 421 (3d Cir. 2000) (citing Black's Law Dictionary for the common usage of the term "pending," which means, among other things, that a complaint has been filed or a summons has been served).

The 50-day gap between the issuance of the 2016 10-K and the announcement of the FTC settlement is safely within the bounds of the FTC's standard protocol. Although the FOM is advisory, the FOM makes clear that the settlement process includes multiple steps. And while

settlement processes can become truncated and expedited at the end of an Administration, the Court declines on this basis alone to draw an adverse inference against the plaintiffs' well-pleaded complaint. At times the complaint refers to the FTC complaint and consent decree as "pending litigation," *e.g.*, Compl. ¶ 126, but the allegations as a whole do not rise or fall on the basis of this semantic distinction. The gravamen of the plaintiffs' complaint is that the defendants were aware of and failed to disclose the impending FTC complaint and consent decree and settlement terms.

Even though the defendants may not have known the precise details of the impending complaint and settlement agreement at the time Mallinckrodt filed its 2016 10-K, it is plausible that the defendants knew on or before November 28, 2016 that the resolution of the FTC investigation was *likely* to have a materially adverse impact on Mallinckrodt. In other words, it is plausible that within 50 days of the filing of the FTC complaint and consent decree the defendants knew that the settlement was substantially certain to occur *and* that its terms would likely have a material adverse impact on the company.

As the complaint alleges, the FTC complaint included detailed factual findings, and the terms of the settlement agreement were significant and complex: it required Mallinckrodt to pay a $100 million fine and divest itself of development rights for Synacthen. It is plausible that the time period it took to negotiate and draft such a settlement was as least as long as the standard timeline outlined in the FOM. And even if the defendants did not know the exact terms of the settlement 50 days before it was filed, it is plausible that defendants knew that the settlement would include either a divestment of Mallinckrodt's valuable assets or a substantial fine, or both. The divestment alone was significant as it exposed Mallinckrodt's largest revenue-producing product to competition it had not previously faced.

The Court emphasizes that its holding is narrow. It concludes that the plaintiffs have plausibly alleged with particularity that the defendants knew with substantial certainty at the time Mallinckrodt's 2016 10-K was filed that (1) a settlement was impending and (2) the terms of that settlement would likely have a material adverse impact on Mallinckrodt's financial condition, results of operations, and cash flows. Thus, the defendants had a duty to disclose something more than what they had disclosed a year earlier (that the FTC investigation "*could* have a material adverse effect on [Mallinckrodt's] financial condition, results of operations, and cash flows," *id.* ¶ 117 (emphasis added)). Based on the facts alleged, the defendants had, at a minimum, an obligation to disclose that the FTC investigation was *likely* to have a material adverse effect on Mallinckrodt. This was a material omission that would have been important to a reasonable investor in making an investment decision. *See Basic*, 485 U.S. at 240.[3] For these reasons, the plaintiffs have met the burden of pleading materiality with respect to the defendants' failure to disclose the fact of the impending FTC complaint and consent decree in Mallinckrodt's 2016 10-K.

b. Misstatement Regarding Acthar's Exposure to Medicare and Medicaid

The plaintiffs argue that Trudeau made a false and materially misleading statement regarding Acthar's exposure to Medicare and Medicaid by understating the percentage of Acthar sales reimbursed by those government programs on an October 6, 2015 call with analysts.

[3] The parties debate whether the plaintiffs' complaint and allegations establish that Mallinckrodt had a duty to disclose the litigation under Item 103 of Regulation S-K, 17 C.F.R. § 229.103. Pls.' Opp'n at 46–47; Def.'s Reply at 9–11. The Court need not resolve the parties' arguments on this point because the defendants' duty to disclose the impending FTC settlement arose from the factual allegations that the defendants knew with substantial certainty at the time they issued Mallinckrodt's 2016 10-K that the filing of the settlement and consent decree were impending.

Compl. ¶¶ 127–51. On that call, Trudeau was asked: "What is your Acthar exposure to Medicare?" *Id.* ¶ 128. In response, Trudeau stated:

> If you look at [Mallinckrodt's] overall business, the combined proportion of our business that goes through Medicare and Medicaid combined it's about a quarter of our business, roughly. Acthar is maybe a little higher than that.

Id. The plaintiffs argue that this statement materially misrepresented the percentage of Acthar sales actually reimbursed by Medicare and Medicaid. *Id.* ¶ 129.

The statement was both false and material. It was false because it understated Mallinckrodt's combined Medicare and Medicaid exposure for Acthar by approximately half the true amount, at best. As alleged, subsequent statements made by Mallinckrodt's own executives establish the falsity of the statement. In November 2016, approximately one year after Trudeau's alleged misstatement, a senior vice president stated that around one-half of Acthar sales were reimbursed by Medicare and Medicaid during the year in question. *Id.* ¶¶ 142–44. And another executive said that Mallinckrodt's "portfolio has shifted a little bit into the mid-40s as it relates to Medicare reimbursement for [Acthar] versus where it was a year and a half, two years ago which was more in that low, mid-30s." *Id.* ¶ 151. If true, Acthar's exposure to Medicare and Medicaid combined would have been in the "low-50s percent range." *Id.* ¶ 144, 151.

The Court is unpersuaded by the defendants' argument that a reasonable investor would not have been misled by Trudeau's statement. "[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor." *Omnicare*, 135 S. Ct. at 1327. Here, Trudeau referred to the "proportion of [the] business that goes through Medicare and Medicaid *combined*." Compl. ¶ 128 (emphasis added). And although the majority of Trudeau's remarks addressed only Medicare, Def.'s Br. at 27–28, in the context in which Trudeau's statement was made, a reasonable investor would have assumed that Trudeau meant to refer to both Medicare

and Medicaid "combined" and that he was able to—and did—differentiate between Medicare and Medicaid when he meant to do so. And although a reasonable investor might not have expected the actual combined figure to be exactly 25% in light of Trudeau's use of the word "roughly," a reasonable investor surely would not have expected the actual figure to be roughly *double* the stated estimate. This is particularly true on an analyst call where Trudeau was presumably expected to be prepared to discuss a wide range of issues, including Acthar's Medicare and Medicaid exposure.

The statement was material because Acthar was Mallinckrodt's "largest single product." Compl. ¶ 142. And the percentage of sales reimbursed by private insurers compared to sales reimbursed by Medicare and Medicaid was a "key metric" for investors, as evidenced by that metric being listed in the risk-factor section of the 2014 joint proxy. *Id.* ¶ 127 (noting in the risk-factor section that "an increase in the proportion of Questcor's Acthar unit sales comprised of Medicaid-eligible patients and government entities" would "indicate[] that having more government reimbursements compared to private insurer reimbursements would be detrimental to the Company's business and future prospects"). Moreover, following the issuance of the Citron Report and the Company's own admissions as to Acthar's Medicare and Medicaid exposure, the price of Mallinckrodt's stock fell 18.4%. *Id.* ¶ 183. The issue of materiality should be resolved as a matter of law only where "the alleged misrepresentations or omissions are so clearly unimportant to an investment decision that reasonable minds cannot differ." *Berg*, 796 F.2d at 495. In this context, "a substantial likelihood exists that a reasonable shareholder would [have] consider[ed] [this information] important in making an investment decision." *Id.*

c. Misstatements and Omissions Regarding Acthar's 2017 Sales Prospects

Finally, the plaintiffs allege that the defendants made a series of material misstatements and omissions in 2017 regarding the long-term prospects for Acthar's sales that included: (1) statements about Acthar's growth across the payer mix, (2) statements about Acthar's strengthened formulary positions and the removal or relaxation of formulary restrictions, (3) statements conveying specific growth projections, and (4) statements about the strength of the scientific evidence supporting Acthar. Compl. ¶¶ 152–161; Pls.' Opp'n at 34. In particular, the plaintiffs allege that the following twenty statements were misleading:

- On a January 19, 2017 call with analysts, Trudeau stated that Acthar was "an exceptionally durable asset" and reiterated that Mallinckrodt would "be able to consistently drive mid-single-digit to low double-digit growth based predominantly on volume." Compl. ¶ 153. (**Statement 1**).

- In a February 7, 2017 press release, the defendants reported a 13.5% net sales increase and issued guidance for the upcoming year that "projected adjusted diluted earnings per share [EPS] of $7.40 to $8.00 per share, and an increase of 4% to 7% for the net sales of the" segment of its brands that markets Acthar. *Id.* ¶ 154. (**Statement 2**).

- On a February 7, 2017 earnings call, Trudeau stated that the company had "seen growth in Acthar in the mid-single-digit to low-double-digit range driven primarily from volume increases in both commercial and public payer plan. . . . We expect these trends to continue." *Id.* ¶ 156. (**Statement 3**).

- On the same February 7, 2017 earnings call, Trudeau stated that Mallinckrodt was "seeing good growth across the range of therapeutic area indication," *id.*, (**Statement 4**), and that they were "seeing very good growth across the payer mix," *id.*, (**Statement 5**).

- The same day Trudeau also indicated that, following the execution of their "contracting and engagement strategy," Mallinckrodt now had "very good growth in both commercial as well as public payers." *Id.* (**Statement 6**).

- On May 8, 2017, Mallinckrodt reported a 9.4% increase for Acthar sales in the first quarter in 2017 over the comparable quarter in 2016, and in a press release Trudeau stated that Mallinckrodt "continue[d] to see strengthening in Acthar formulary positions and access for appropriate patients in both the commercial and public environments, including relaxation or removal of previous formulary restrictions . . ." *Id.* at 157. (**Statement 7**). Trudeau made similar remarks later on, and also stated that the company "believe[d] the high unmet medical need and low market penetration in most indications will support increased demand growth for Acthar." *Id.* (**Statement 8**).

- The same day on an earnings call, Trudeau reiterated that the company was still achieving 60% commercial lives under contract for Acthar, *id.* ¶ 158, (**Statement 9**), and that Mallinckrodt had "good confidence that we can continue to drive the long-term growth rate expectations in the mid-single to low double-digit range," *id.*, (**Statement 10**). Harbaugh also stated that Mallinckrodt's rebating strategy "was fully considered in the guidance that we provided." *Id.* (**Statement 11**).

- On May 19, June 6, and June 22, 2017, the company issued press releases in response to short sellers and stated that: Acthar's efficacy in approved indications was strongly supported by evidence, *id.* ¶ 159, (**Statement 12**), the company had expanded the number of commercial lives under contract to 60%, *id.*, (**Statement 13**), and in the commercial market, "the majority of payers have an established pathway for the use of H.P. Acthar Gel in those patients for whom it is appropriately prescribed – those with conditions covered by the FDA-approval label and for whom the product's extensive existing data and clinical experience support H.P. Acthar Gel's use as a proven therapy," *id.*, (**Statement 14**).

- In those same press releases, the company stated that, as to commercial payers, the "prior-authorization and reimbursement processes used by commercial payers rely on" criteria for approving Acthar on a given insurer's formulary and that "these criteria are not bypassed through co-pay programs." *Id.* (**Statement 15**).

- On August 8, 2017, Mallinckrodt announced second quarter results in a press release. The company reported that Acthar net sales had increased 7.1% in the second quarter period over the same quarter in 2016, and the defendants reiterated EPS guidance of $7.40 to $8.00 from February 2017, despite the fact that Mallinckrodt's net sales were down 4.9% in the quarter compared to the same quarter in 2016 and that diluted EPS had dropped from $2.03 to $1.85. *Id.* ¶ 160. (**Statement 16**).

- On an earnings call that day, Trudeau stated that Acthar's 7.0% growth in the second quarter was "within our long-term range of mid-single to low double digits," noting that while increased price was the "driver" during the second quarter, the Company's expectations "longer term are that growth will be predominantly volume-driven, and we expect to see that in the back half of the year." *Id.* ¶ 161. (**Statement 17**).

- On the same call Trudeau stated that Mallinckrodt had "been building on the strengthening formulary positions we've reported in the first quarter and are pleased to see that new patient prescriptions have reached their highest point in the last 12 months across the majority of promoted indications as we reach a broadening base of prescribers with additional data." *Id.* (**Statement 18**).

- On the same call Trudeau stated, in response to a question about Acthar, that "[i]n terms of the growth, we would expect kind of similar type growth rates regardless of the payer mix, whether it's federal reimbursed patients, Medicare primarily or commercial patients, we would expect similar growth rates regardless of the type of reimbursement that occurs." *Id.* (**Statement 19**).

- On the same call Trudeau further said that "we continue to see good, strong formulary positioning, strengthening formulary positions that we alluded to in the first quarter," and that with the new data the company had published on Acthar, "we wouldn't expect anything different here going forward." *Id.* (**Statement 20**).

The plaintiffs claim that these statements were materially false and misleading because they omitted key information and thereby misled investors into believing that an increase in Acthar prescription levels would translate to a corresponding increase in net sales over the course of 2017. *Id.* ¶ 162. According to the plaintiffs, Mallinckrodt's statements about Acthar's efficacy being "strongly supported by evidence" omitted serious weaknesses in the scientific evidence for most indications, as later critiqued by a prominent medical journal. *Id.* ¶ 162. Moreover, major private insurers were only approving Acthar for a limited range of treatments, and others were placing added restrictions on its use, *id.* ¶¶ 163–67, making Mallinckrodt's statements about increasing market positioning misleading.

The plaintiffs further allege that the falsity of the defendants' statements came to light on November 17, 2017, when the company reported that net sales for Acthar had declined 5.6% in the third quarter of 2017 from the comparable quarter in 2016. *Id.* ¶ 168. During an earnings call that day, Trudeau stated that Acthar sales had slowed in part due to "a volume decline" attributable to "an increasing number of prescriptions going unfilled beyond the level we had seen previously." *Id.* ¶ 169. Trudeau noted that these issues would lead to lower net sales of Acthar in the fourth quarter of 2017. *Id.* He also stated that Acthar "continues to experience payer pressures," that those pressures would "continue to be more challenging," and that Mallinckrodt "expect[ed] payers to put more and more hurdles in front of patients getting these reimbursements." *Id.* Trudeau attributed the company's situation to a "combination of both those payer pressures, plus . . . the additional issue that we're seeing with these patient prescriptions going unfilled." *Id.*

As discussed more fully below, before the November 17, 2017 announcement, the defendants made a series of material misstatements about Acthar's growth across the payer mix, the strengthening of formulary positions, the removal of previous formulary restrictions, the expansion of commercial lives under contract, and the growth levels of Acthar sales. *Id.* ¶ 189.

i. Statements about Acthar's growth across the payer mix and about Acthar's strengthened formulary positions and the removal and relaxation of formulary restrictions

The plaintiffs identify Statements 3, 5, 6, 7, 9, 13, 14, 15, 17, and 19 about Acthar's growth across public and private plans as false or misleading. The plaintiffs also identify Statements 4, 7, 14, 17, 18, and 20 about Acthar's claimed strengthened formulary positions and the removal or relaxation of formulary restrictions as false or misleading. They argue that these statements conveyed to the market that (1) Acthar was being included in more private insurance companies' formularies of approved medications for certain conditions and (2) insurers had expanded the circumstances under which they would approve and provide reimbursement for Acthar. *See* Compl. ¶ 161 n. 28.

The Court agrees that the plaintiffs have pleaded sufficient facts establishing materiality as to both categories of alleged misstatements. According to the plaintiffs, at the time the defendants made the statements, major private insurers were not expanding reimbursements for most of Acthar's treatments; rather, private insurers were cutting back on Acthar reimbursements. *Id.* ¶¶ 163–66. Thus, the alleged statements about Acthar's growth were either false or misleading. For example, in Statement 5, Trudeau stated that Mallinckrodt was "seeing very good growth across the payer mix." *Id.* ¶ 156. But, according to the plaintiffs, at the time, private insurers were placing increased restrictions on Acthar's use and "had approved reimbursement for Acthar for only a few of its indications." *Id.* ¶ 163. Insurance company data allegedly shows that Mallinckrodt was not in fact experiencing "good growth" or "strengthening

positions," *e.g.*, *id.* at ¶¶ 156–57, but was instead experiencing stagnation or even contraction among major private payers. At that time, major insurers were actually placing increasing formulary restrictions on Acthar's use. *Id.* ¶¶ 162–67. Trudeau also admitted after the November 17, 2017 corrective disclosure that Acthar had experienced payer pressures and that those pressures were expected to "continue to be more challenging." *Id.* ¶ 169. Although the defendants' earlier disclosures about "payer-driven restrictions" and "payer pressures" identified the general risk factor, the defendants' representations that they were "seeing good growth across the payer mix" and were projecting "similar growth rates" across public and private payers were materially false and misleading if, as plaintiffs allege, insurers were limiting their approval policies for Acthar's use. *See id.* ¶ 167. And there can be little dispute that these misstatements were material. The fact that Acthar was realizing a contraction for private payer reimbursements and a weakening or stagnation of formulary positions would have significantly altered the total mix of information for a reasonable investor.

The defendants counter with three arguments. *First*, the defendants argue that the plaintiffs cannot state a material omission with respect to insurer restrictions because the restrictions were well known to the market and had been disclosed to the market on several occasions. Def.'s Br. at 28–29. In support, the defendants point to information available on insurer public websites, *id.* at 28 (citing Compl. ¶¶ 163–66), disclosures in Mallinckrodt's prior SEC filings stating that "Acthar will likely be subject to payer-driven restrictions," *id.* at 29, and statements by Trudeau in 2015 and 2017 highlighting payer pressures as a recurring challenge, *id.* at 29–30.

At this early stage, however, the Court cannot conclude that Acthar's claimed growth across the payer mix and improving formulary positions were not misleading solely because

some information about insurer restrictions was in the public domain. For one, this would necessarily assume that investors understood and digested complex health insurance data replete with medical terminology. *See Pub. Employees Ret. Sys. of Mississippi v. Amedisys, Inc.*, 769 F.3d 313, 323 (5th Cir. 2014) (observing that investors cannot be expected to comb through "publicly available Medicare records" that involve "complex economic data understandable only through expert analysis"); *see also, e.g.*, Compl. ¶ 164 (outlining Cigna's complex coverage policies). And even if this public information were in a form readily digestible by investment analysts, it would require yet another leap to expect investors to have fact-checked the defendants' representations about their continuing or strengthening positions in the private payer environment over time. This exercise would have seemingly required investors to conduct a market-wide historical analysis of aggregate payer restrictions on Acthar over many years. As alleged, major private insurers were narrowing rather than expanding coverage of Acthar, and the defendants' statements about payer pressures and restrictions as general risk factors failed to disclose this critical fact.

Second, the defendants argue that general statements by Trudeau, such as those regarding "good growth" across the payer mix and "strengthening positions," were immaterial as a matter of law because they were statements of general corporate optimism that are inactionable puffery. *Id.* at 30. Under the law in this Circuit, the critical inquiry in evaluating whether a statement is a generalized statement of corporate optimism is "whether the statement could have misled a reasonable investor" in "the context in which it was made, according to the allegations in the complaint." *In re Harman*, 791 F.3d at 109 (citing *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Companies, Inc.*, 75 F.3d at 811 (2d Cir. 1996) (internal quotation marks omitted)). In *In re Harman*, the D.C. Circuit held that a statement that sales were "very

strong" was "plausibly understood as a description of historical fact rather than unbridled corporate optimism, *i.e.*, immaterial puffery." *Id.*

Here, whether Mallinckrodt was experiencing "good growth" across the payer mix or enjoying "strengthening positions" were representations of objective fact that can be tested against the well-pleaded allegations of the complaint. As discussed, the complaint alleges that major insurers were placing increased restrictions on Acthar, Compl. ¶¶ 162–67, and Trudeau indicated that increased payer pressures was one of the reasons that Acthar had begun underperforming by the end of 2017, *id.* ¶ 169. Thus, Trudeau's statements about good growth and strengthening positions across the payer mix were material misstatements, not merely immaterial puffery.

Third, the defendants argue that statements such as Statements 13 and 14 (that refer to increases in "commercial lives under contract" and "a majority of insurers hav[ing] an established pathway" for using Acthar) were not false. *Id.* at 30. But the defendants ignore that a plaintiff need not establish materiality by showing that a statement was false. A plaintiff also can show that a statement was materially misleading because it omitted a material fact that a defendant had a duty to disclose. *See Basic*, 485 U.S. at 224 (noting that 10b–5 prohibits "the making of any untrue statement of a material fact or the omission of a material fact that would render statements made not misleading"); *see also In re Time Warner*, 9 F.3d at 268 (reasoning that the "duty to disclose arises when disclosure is necessary to make prior statements not misleading").

Here, the plaintiffs sufficiently allege that Mallinckrodt's statements about gaining private commercial lives in early 2017 were materially misleading because they omitted key facts. *See* Compl. ¶ 163. As to statements 13 and 14 in particular, the complaint alleges that

Mallinckrodt omitted the fact that many private insurers in 2017 "had approved reimbursement for Acthar for only a few of its indications," *id.*, and the complaint alleges that the "reality was that many major insurers were continuing to approve Acthar only for a limited range of treatments, and others were continuing to place severe restrictions on the duration of Acthar treatments, both of which created an undisclosed risk that a substantial portion of the prescriptions written for Acthar would never be filled and Acthar sales could decline," *id.* ¶ 167. These undisclosed facts allegedly concealed a risk that Trudeau ultimately acknowledged as a cause for Acthar's declining sales in the third quarter of 2017. Further, the defendants represented to the market that Mallinckrodt was experiencing "good growth" across private payers at a time when private payer pressure and restrictions were allegedly increasing or stagnating. The plaintiffs have thus plausibly alleged that the defendants' failure to disclose material information about private payer restrictions made their earlier "statements about improved access to private insured lives" false and misleading. *Id.*

In sum, the plaintiffs have pleaded facts that raise a plausible inference that the defendants made materially false statements and omitted key information that made their early 2017 statements about Acthar's growth across the payer mix materially misleading. This information certainly would have been viewed by the reasonable investor as having significantly altered the total mix of information. Thus, the plaintiffs have met their burden of pleading materiality with respect to the 2017 statements about Acthar's growth across the payer mix.

ii. Growth projections

The plaintiffs next argue that Statements 1, 2, 3, 8, 10, 11, 16, and 17, which relate to Mallinckrodt's growth projections, were false and misleading. Statements 1, 3, 10, and 17 involve the defendants' projection of mid-single-digit to low-double-digit growth. Statements 1,

3, and 17, in particular, tie the defendant's growth projections to their claim that growth would be driven by volume. Statements 2 and 16 involve earnings per share guidance. Statement 11 presented the defendant's guidance that they had taken their rebating strategy into account when assessing growth. And Statement 8 expressed the defendant's belief about factors that would lead to increased future demand for Acthar. The plaintiffs allege that the defendants 2017 projections were misleading because they led the market to believe that Acthar's future growth would be strong but failed to disclose that Acthar's acceptance with insurers and the medical community was declining. At the end of 2017, when the defendants eventually disclosed Acthar's increasing payer pressures while reporting a sales decline, Mallinckrodt's stock price plummeted.

The defendants counter that these alleged misstatements are shielded from liability under the PSLRA's safe harbor provision, *see* Def.'s Br. at 31; 15 U.S.C. § 78u–5(c)(1)(A)(i), but the Court is unpersuaded. To receive safe-harbor protection, a statement must be "identified as . . . forward-looking and accompanied by *meaningful* cautionary statements identifying *important* factors that could cause actual results to differ materially from those in the forward-looking statement." *In re Harman*, 791 F.3d at 95 (citations and internal quotation marks omitted, emphasis in original). For cautionary statements to be "meaningful," there must be substantive warnings "specific to the Company and tailored to the specific forward-looking statements, not mere boilerplate, and consistent with the historical facts when the statements were made." *Id.* at 103.

To support their safe harbor argument, defendants first note that Statements 1, 3, 10, 11, and 17 were oral statements about future growth made on calls with investors. Before each of

these statements, the defendants advised analysts of certain risks.[4] For example, on the January 19, 2017 conference call preceding Statement 1, *see* Compl. ¶ 153, the defendants advised investors of the following:

> Before we get started, on the call, you'll hear us making some forward-looking statements, and it's possible that actual results could be materially different from our current expectations. Please note that we assume no obligation to update the information contained in these forward-looking statements even if actual results or future expectations change materially. We ask you to please refer to the cautionary statements contained in our SEC filings for a more detailed explanation of the inherent limitations of such forward-looking statements.

See Def.'s Br. at Ex. 51; *see also id.* at Ex. 49, 52, and 53 (citing identical warnings before each conference call). The defendants also note that the SEC filings cited in the complaint and referred to on the calls "listed pages and pages of risk factors," *id.* at 31, that could cause "actual results to vary materially from recent results or from our anticipated future result," *id.* at Ex's. 10, 16, 24 (citing identical statements in Mallinckrodt's 2014, 2015, and 2016 10-Ks). In its 10-Ks, Mallinckrodt disclosed that its "ability to maintain and increase net sales from [its] products depends on several factors, including . . . [its] ability to achieve hospital formulary acceptance, and maintain reimbursement levels by third-party payors." *Id.* at 32. The defendants contend that these disclosures, which "flagged difficulties in achieving acceptance on payer formularies," Def.'s Reply at 21, satisfied the PLRA's safe harbor provision because they contained "information that [was] tailored to [Mallinckrodt's] status at [the] particular time," *id.* at 22 (citing *In re Harman*, 791 F.3d at 101).

[4] The Court notes that the defendants appear to argue for safe-harbor protections on the basis of these preliminary remarks only for the challenged "oral statements," Def.'s Br. at 31, not for the challenged statements in the written press releases (Statements 2, 8, 16).

The defendants' arguments miss the mark for three reasons. *First*, much of the cautionary language presented at the beginning of the investor calls constituted standard boilerplate language lacking the necessary specificity to apprise the market of the existing risks. *See In re Harman*, 791 F.3d at 97, 103–04 (noting that boilerplate cautionary language referencing general risk factors in an Annual Report was insufficient for safe-harbor protection).

Second, cautionary statements relating to the risk that Acthar sales could be impacted by formulary acceptance and third-party reimbursement levels "were misleading in light of historical fact[s]." *Id.* at 104. At the time the defendants made the 2017 statements about improved formulary positioning and volume-driven growth, formulary restrictions were allegedly increasing and eventually caused a decline in Acthar sales. According to the plaintiffs, the defendants knew that private insurers were only approving Acthar for a limited number of uses and were placing further restrictions on its use, yet in each of Mallinckrodt's 2014, 2015, and 2016 10-Ks they continued to mislead the public about Acthar's formulary restrictions improving. *See id.* at 107 (noting "that the Company's cautionary statements remained unchanged despite a significant change in circumstances of material importance to an investor"). The defendants did not disclose until the end of 2017 that payer pressures on Acthar were actually increasing.[5]

Third, the defendants never disclosed the risk that private payer formulary restrictions could lead to reductions in Acthar sales (even in an environment where prescription levels increased). And they pointed to volume-driven growth as a key factor underlying their

[5] To the extent that the defendants are arguing that the plaintiffs have incorrectly argued "fraud by hindsight," Def.'s Br. at 30–31, that argument fails because the defendant's growth projections were based on allegedly untrue statements about relaxed insurer formularies and growth across the payer mix in early 2017. By late 2017, increased prescription levels did not lead to the "volume-driven growth" the defendants had been trumpeting to investors to justify their growth projections.

projections. In this context, Trudeau's reference (at the beginning of the January 19, 2017 investor call) to boilerplate warnings in Mallinckrodt's SEC filings was not adequate to protect the projections from scrutiny under the PSLRA's safe-harbor provision. For these reasons, the plaintiffs have met their burden of pleading materiality with respect to the 2017 growth projections.

iii. Statement that Acthar's efficacy was "strongly supported by evidence"

The plaintiffs argue that Statement 12 in Mallinckrodt's May 19, 2017 press release (that Acthar was "strongly supported by evidence") was materially false and misleading because the scientific evidence for Acthar's "efficacy in its approved indications" was lacking. Pls.' Opp'n at 36. In support, the plaintiffs note that at the time the defendants made the statements, authors of a prominent medical journal had put forth a "serious critique" of Mallinckrodt's evidence. Compl. ¶ 162 n.29.

The Court disagrees with the plaintiffs. Viewed in context, Statement 12 could not have been materially misleading to a reasonable investor. The defendants issued the May 19, 2017 press release in order to "Refute Short-Seller Claims," and the press release included a range of topics. *See* Def.'s Br. at Ex. 55. It stated that "[Acthar's] efficacy in its approved indications is strongly supported by evidence," it discussed the FDA's 2010 review of the label, and it revealed the FDA's determination that "there in fact was sufficient scientific and clinical evidence to support the 19 indications now in the current label." *Id.* In context, it is clear that Mallinckrodt was simply expressing an optimistic opinion about the strength of its evidence based on the FDA's prior study of Acthar. Because this statement of opinion relied on true facts about the FDA's study and approval of Acthar, the Court cannot conclude that Mallinckrodt "had no

reasonable basis for it." *In re Lehman Bros. Sec. & ERISA Litig.*, 131 F. Supp. 3d 241, 251 (S.D.N.Y. 2015).

Moreover, the other related statements Mallinckrodt made in the same press release (about "conditions covered by the FDA-approved label" and Acthar's "extensive existing data and clinical experience support H.P. Acthar Gel's use as a proven therapy") were not misleading. To support its opinion that Acthar's efficacy was "strongly supported by evidence," Mallinckrodt pointed to the FDA's 2010 approval process for the approved indications and to clinical experience and data. Contrary to the plaintiffs' suggestion, Mallinckrodt had no duty to air every critique from the medical community. Because Mallinckrodt had a reasonable basis for its opinion that Acthar's use was strongly supported by evidence, and its statement would not have lead a reasonable investor to believe that there could be no possible weakness in the data for any of the approved indications, Statement 12 was not materially misleading.

Further, the plaintiffs do not explain how the defendants would have been able to account for the alleged weaknesses in some of their studies. For one, both the medical journal article critique, Compl. ¶ 162, and the 60 Minutes special, Compl. ¶ 79 n. 13, that the plaintiffs cite were published *after* Mallinckrodt issued its 2017 press releases. And the medical journal article merely pointed out that there were weaknesses in the types of studies used for some, but not all, of Acthar's approved indications. The defendants never suggested that the studies for each indication were of the highest possible scientific quality. Instead, they pointed to the FDA approval and clinical data as support for its claim that Acthar's efficacy, in general, was strongly supported by evidence. It is unclear what, if anything, the defendants could have done to "qualify," Pls.' Opp'n at 37, its opinions about the study quality other than to engage in public self-criticism by listing all of the weaknesses in its clinical data for the world to see, which the

company had no duty to do, *see Kowal*, 16 F.3d at 1277. The securities laws do not impose a blanket "duty to disclose any and all material information," *Matrixx*, 563 U.S. at 44, much less every possible weakness of study data for every FDA-approved indication.

In addition, the PSLRA requires plaintiffs to "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), but the complaint does not explain why the failure to disclose the critiques of evidence for Acthar's efficacy would have prevented the market from adequately apprising the risk that allegedly led to the stock drop. The complaint alleges that the omission of negative critiques regarding Acthar's evidence "misled the market into believing that as Acthar prescription levels increased, so too would its net sales." Compl. ¶ 162. But it does not explain why or how the critiques of Mallinckrodt's data would have corrected a false market perception about how the increase of prescription levels would relate to net sales. The complaint does not, for example, allege that hidden weaknesses in the evidence for Acthar motivated insurers' decisions about the circumstances in which they would reimburse payments for Acthar prescriptions.

The plaintiffs have not met their burden of explaining why the defendants' optimistic opinion about the evidence of Acthar's efficacy (supported by an FDA study) misled the market in assessing the relationship between increased prescription levels and net sales. Thus, the plaintiffs' claims with respect to the statement that Acthar's efficacy was "strongly supported by evidence" will be dismissed.

2. Scienter

A plaintiff bringing a claim under Section 10(b) must sufficiently plead scienter and must state "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," 15 U.S.C. § 78u–4(b)(2), defined as a "state embracing intent to deceive,

manipulate, or defraud," *Tellabs*, 551 U.S. at 319 (citation omitted). To survive a motion to dismiss, a plaintiff must plead "an inference of scienter *at least as likely* as any plausible opposing inference." *Id.* at 328 (emphasis in original). In determining whether a plaintiff has sufficiently pleaded scienter, the Court must consider "not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged." *Id.* at 314 (explaining that "[a]n inference of fraudulent intent may be plausible, yet less cogent than other, nonculpable explanations for the defendant's conduct"). The Court's "inquiry is inherently comparative," as it must determine "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 323 (emphasis in original).

The Circuits are divided on how a plaintiff can establish a "strong inference" of scienter, and the D.C. Circuit has not yet articulated precisely how a plaintiff can satisfy its burden to plead scienter. However, the Circuit has stated that conduct amounting to "intentional wrongdoing or extreme recklessness satisfies the standard" for scienter. *Liberty Prop. Tr. v. Republic Properties Corp.*, 577 F.3d 335, 342 (D.C. Cir. 2009) (internal quotation marks and citation omitted); *see also Dolphin & Bradbury, Inc. v. SEC*, 512 F.3d 634, 639 (D.C. Cir. 2008). And district courts in this circuit have held that scienter can be shown "by alleging facts to show that defendants had both motive and opportunity to commit fraud or . . . facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *SEC v. e-Smart Techs., Inc.*, 31 F. Supp. 3d 69, 81 (D.D.C. 2014) (internal quotation marks and citation omitted). This framing is in line with the framework adopted by the Second Circuit. *See In re Baan Co. Sec. Litig.*, 103 F. Supp. 2d 1, 19 (D.D.C. 2000) (explaining the Second Circuit's approach allowing plaintiff to establish scienter "by alleging facts to show either (1) that the defendants

had motive and opportunity to commit fraud or (2) strong circumstantial evidence of conscious misbehavior or recklessness").

Recklessness "is an extreme departure from the standards of ordinary care . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Dolphin & Bradbury*, 512 F.3d at 639 (internal quotation marks and alterations omitted). It is a "lesser form of intent, implying the danger was so obvious that the actor was aware of it and consciously disregarded it." *Id.* (citation omitted). The plaintiffs contend that they have established scienter "by direct and circumstantial evidence of the defendants' actual knowledge and/or extreme recklessness" and that allegations of the defendants' motive and opportunity "provide further support for an already strong inference" of scienter. Pls.' Opp'n at 62.

a. The Competitive Environment for Acthar

Because the Court concludes, *infra*, that the plaintiffs have not pleaded facts sufficient to establish loss causation with respect to the defendants' alleged (1) failure to disclose the fact of the FTC investigation in the 2014 joint proxy, it need not decide whether the plaintiffs have met their burden with respect to scienter on that claim. As to the remaining alleged misstatements and omissions regarding Acthar's competitive environment, the Court holds that the plaintiffs have failed to meet their burden on scienter with respect to both the defendants' alleged (2) failure to disclose that the sole worldwide manufacturer of Synacthen would cease manufacturing it in 2016 and (3) misstatement of Mallinckrodt's competitive positioning pertaining to Acthar. However, the Court holds that the plaintiffs have met their burden on scienter with respect to the defendants' alleged (4) failure to disclose the impending FTC complaint and consent decree in Mallinckrodt's 2016 10-K.

The plaintiffs have not adequately pleaded a strong inference of scienter with respect to the alleged failure to disclose in the 2014 proxy that the sole worldwide manufacturer of Synacthen would cease producing it in 2016. As explained, the defendants did not have a duty to disclose this fact to shareholders in 2014 as the information would not have significantly altered the total mix of information available to investors and thus was not materially misleading. And even if the defendants' failure to disclose this information was misleading, the claim could not proceed because the circumstances taken as a whole do not satisfy the scienter standard. The more compelling inference is that the defendants considered the information to be either too distant in the future to raise a present-day concern, or an issue that could be addressed by identifying a new manufacturer. For these reasons, the plaintiffs have not established a strong inference of scienter for this alleged material omission.

The plaintiffs also have not pleaded a strong inference of scienter for their alleged misstatements about Mallinckrodt's competitive positioning pertaining to Acthar. As noted, the defendants did not have a duty to disclose that Acthar's success was predicated on the defendants' alleged hatching of an uncharged, continuing scheme to violate the antitrust laws. And even if Mallinckrodt did have a duty to disclose its plans about how it would compete the two drugs, the plaintiffs have failed to allege scienter. They point to a former vice president's statement that Trudeau "would have had to approve any" plan not to develop Synacthen to compete with Acthar, Pls.' Opp'n at 56 (citing Compl. ¶¶ 88–91), but that statement alone does not establish the existence of an anticompetitive scheme or provide particularized facts supporting a strong inference of scienter. The more compelling inference from the facts alleged is that the defendants did not disclose the existence of an anticompetitive scheme because none existed and that they reasonably believed that their business decisions following the Questcor

acquisition did not violate the antitrust laws. For those reasons, the plaintiffs have failed to adequately allege scienter with respect to the claim that the defendants knowingly or recklessly failed to disclose their involvement in an anticompetitive scheme.

However, the plaintiffs have pleaded a strong inference of scienter with respect to the failure to disclose in Mallinckrodt's 2016 10-K information about the impending FTC settlement. The complaint plausibly alleges that the defendants knew with substantial certainty that a settlement and consent decree were impending and that the terms of the settlement would likely have a material adverse impact on Mallinckrodt. As explained, this knowledge gave rise to a duty to disclose something more than that the FTC investigation *could* have an adverse effect on Mallinckrodt. The defendants' failure to disclose that the FTC investigation would likely have an adverse effect on Mallinckrodt raises a compelling inference that the defendants, at a minimum, recklessly disregarded their obligation to disclose material information regarding the investigation. And their subjective "belie[f] [that] they had nothing to hide and acted accordingly," Def.'s Br. at 40–41, does not negate the cogent inference that they acted recklessly in failing to disclose this information to investors.

To be clear, the Court does not find that the defendants had certain knowledge of any particular term of the settlement. Rather, the Court concludes—based on the factors noted above: (1) the complex and significant terms of the settlement agreement, (2) the typical length of the FTC's settlement process, and (3) the strong likelihood that a settlement would include either a divestment of Mallinckrodt's valuable monopoly position or a sizeable fine, or both—that the allegations in the complaint raise a compelling inference of recklessness that is at least as compelling as the defendants' asserted inference of nonculpable conduct. The plaintiffs have

thus adequately plead scienter with respect to the defendants' failure to disclose the impending FTC filing in the 2016 10-K.

b. Medicare and Medicaid Reimbursements

The Court also concludes that the defendants acted with scienter when they misstated the amount of reimbursement for Acthar by Medicare and Medicaid on an October 2015 conference call. Trudeau's statement was not an estimate that turned out to be wrong in retrospect, but rather a false statement of present fact regarding a key metric that investors were interested in knowing, *see* Pls.' Opp'n at 58, and that was noted as an important metric by the defendants in the 2014 joint proxy statement, Compl. ¶¶ 24, 127. As alleged, Mallinckrodt executives intentionally presented data about Acthar's exposure to Medicare and Medicaid during an investor call, *id.* ¶ 22, and the figures Trudeau trumpeted during the call were roughly half as much as the actual figures, *id.* ¶ 29, as Mallinckrodt's own executives acknowledged, Pls.' Opp'n at 59 n.40 (citing Compl. ¶¶ 142–45, 212).

Further, the question about Acthar's Medicare and Medicaid exposure on the October 2015 investor call was one that was "readily anticipated." Pls.' Opp'n at 58 (citing Compl. ¶¶ 22, 24, 29, 127–29, 137). During the call, Trudeau made introductory statements about Acthar's contribution, and he spent significant time discussing Acthar's competitive environment. Pls.' Opp'n at 8–9. Also, company "management was provided with up-to-date information concerning its sales of Acthar." Compl. ¶ 212. Even if Trudeau did not know the precise figures when he made the statement, his statement and the defendants' failure to correct it was recklessness. As alleged, the defendants "knew facts or had access to information suggesting that [their] public statements were materially inaccurate," Pls.' Opp'n at 59 n.40 (quoting *Burman v. Phoenix Worldwide Indus., Inc.*, 384 F. Supp. 2d 316, 333 (D.D.C. 2005)

(alteration omitted)), and they took no corrective action following the misstatement. Yet approximately one year later, after the Citron Report was released, Mallinckrodt executives admitted that Acthar's exposure to Medicare and Medicaid was roughly double Trudeau's estimate. Compl. ¶¶ 142–45, 212.

Contrary to the defendants' suggestion, this is not a case "[w]here the allegation of recklessness is supported by nothing other than the fact of inaccuracy, and [where] the statements are, at worst, only slightly inaccurate." *Furher v. Ericsson LM Tel. Co.*, 363 F. App'x 763, 765 (2d Cir. 2009). Rather, the plaintiffs have alleged facts showing that Trudeau's public statements were false and significantly lower than those that his own executives (and the Citron Report) disclosed a year later. It is more than plausible that Trudeau and other company executives had access to accurate information before the investor call and were prepared to speak about Acthar's Medicare and Medicaid exposure. Moreover, the defendants' failure to correct Trudeau's misstatement shortly after the call raises a cogent and compelling inference that the defendants acted at least recklessly. This inference is at least as compelling as the defendants' suggestion that Trudeau's estimate was imprecise but within the bounds of a reasonable estimate. In short, the defendants' departure from ordinary care "present[ed] a danger of misleading buyers or sellers that [was] either known to the defendant or so obvious that [he] must have been aware of it." *Dolphin & Bradbury*, 512 F.3d at 639. For these reasons, the plaintiffs have adequately pleaded scienter with respect to Trudeau's misstatement about Acthar's exposure to Medicare and Medicaid.

c. 2017 Prospects for Acthar

The plaintiffs also have adequately pleaded a strong inference of scienter sufficient to survive the defendants' motions to dismiss with respect to the 2017 statements about Acthar's

growth and formulary positions. As alleged, when the defendants made statements in 2017 about Acthar's growth across the payer mix, strengthening of formulary positions, and growth projections, private insurers were not expanding their reimbursements of Acthar, but instead were placing more restrictions on the drug. Pls.' Opp'n at 59 (citing Compl. ¶¶ 162–65).

For the reasons discussed above, a reasonable investor would not have had sufficient information to determine that formulary restrictions were actually increasing over time, and it was reasonable for investors to rely on the defendants' contrary representations. The fact that formulary positions were not strengthening in early 2017, as the defendants repeatedly stated, is highly suggestive of at least recklessness on their behalf. And that inference is at least as compelling as the defendants' competing inference that they believed that no further disclosure was required because the market already knew the information it needed to evaluate the risk of insurance formulary restrictions. This is especially true in light of defendants' statement of present fact that formularies were improving when insurers were instead becoming more restrictive.

However, the plaintiffs have not pleaded a strong inference of scienter with respect to the statement that the evidence for Acthar's efficacy was strongly supported by evidence. First, as explained, the defendants did not have a duty to disclose any and all weaknesses in the scientific evidence for each of the FDA-approved indications. Second, the plaintiffs have not alleged that Mallinckrodt had knowledge of the specific medical journal article or press report (or the research underlying either) that the plaintiffs say exposed serious weaknesses in Mallinckrodt's evidence for Acthar. The more compelling inference is that Mallinckrodt supported its opinion about the strength of the evidence for Acthar's efficacy with true statements based on the FDA's

study. Mallinckrodt's failure to catalogue each criticism of its study data does not support a strong inference of scienter.

3. Loss Causation

To establish the required element of loss causation, the plaintiff has "the burden of proving that the act or omission of the defendant alleged to violate [§ 10(b)] caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u–4(b)(4). In other words, the plaintiff "must prove that the defendant's fraud caused an economic loss." *See Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 338 (2005). As "[t]he Supreme Court has made clear, for a plaintiff to sufficiently plead loss causation, there must be an actual loss." *Waters v. Gen. Elec. Co.*, 2010 WL 3910303, at *10 (S.D.N.Y. Sept. 29, 2010) (citing *Dura*, 544 U.S. at 338), *aff'd sub nom. GE Inv'rs v. Gen. Elec. Co.*, 447 F. App'x 229 (2d Cir. 2011). "A plaintiff must allege that the subject of the fraudulent statement or omission was the cause of the actual loss suffered, i.e., that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Freeland v. Iridium World Commc'ns, Ltd.*, 545 F. Supp. 2d 59, 80 (D.D.C. 2008) (citations and alterations omitted). "Thus, loss causation analysis in a fraud-on-the-market case focuses on the following question: even if the plaintiffs paid an inflated price for the stock as a result of the fraud . . . did the relevant truth eventually come out and thereby cause the plaintiffs to suffer losses?" *FindWhat Inv'r Grp. v. FindWhat.com*, 658 F.3d 1282, 1312 (11th Cir. 2011).

For the reasons that follow, the Court holds that the plaintiffs have failed to plead loss causation for the defendants' alleged failure to disclose the FTC subpoena and investigative demand in the 2014 joint proxy and for the defendant's alleged failure to disclose that the sole worldwide manufacturer of Synacthen would cease manufacturing it in 2016.

a. Competitive Environment

As to the defendants' alleged failure to disclose the FTC subpoena and investigative demand in the 2014 joint proxy, the plaintiffs have not alleged any specific disclosures that resulted in a stock price decline. The plaintiffs seemingly concede the point, but argue that this fact "is not dispositive of loss causation" because "there were many positive disclosures made in the [2014 10-K] that would have served to prop up the price of Mallinckrodt stock even with the disclosure of the FTC investigation." Pls.' Opp'n at 63. But whether other positive information "is the reason why an actual loss did not occur is outside the scope of the loss causation analysis," *Waters*, 2010 WL 3910303, at *10; *see also In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 392 (9th Cir. 2010) ("To adequately plead loss causation . . . a plaintiff must allege that the share price fell significantly after the truth became known."); *Glaser v. Enzo Biochem, Inc.*, 464 F.3d 474, 478 (4th Cir. 2006) ("[T]o properly plead loss causation . . . a plaintiff must allege that the price fell after the truth came to light about a misrepresentation.").

Here, the plaintiffs point to no facts in the complaint that suggest that the alleged corrective disclosure in late 2014 caused any actual harm to investors. And even assuming that the plaintiffs' "prop up" theory could satisfy their burden, the plaintiffs allege no particularized facts suggesting that good news at the time of the corrective disclosure stood to "prop up" Mallinckrodt's stock price. Indeed, in the "Loss Causation" section of the complaint, the plaintiffs allege that a series of corrective disclosures beginning in August 2015 revealed the truth about Mallinckrodt's operations pertaining to Acthar, but they fail to allege that the revelation of the FTC investigation in late 2014 corrected a prior artificially inflated stock price or that good news revealed in late 2014 propped up Mallinckrodt's stock price. Thus, the

plaintiffs' claim with respect to the failure to disclose the FTC investigation in the 2014 proxy will be dismissed for failure to plead loss causation.

For the same reason, the plaintiffs' claim with respect to the defendant's alleged failure to disclose that the sole worldwide manufacturer of Synacthen would cease manufacturing it in 2016 will also be dismissed for the additional reason that the plaintiffs fail to plead loss causation. The plaintiffs allege that this fact was disclosed in November 17, 2015, Compl. ¶¶ 106, 109, but the complaint fails to allege any drop in the company's stock price as a result of the alleged corrective disclosure.

However, the plaintiffs do allege a stock price decline following the disclosure of the 2017 FTC complaint and consent decree, Compl. ¶ 207, and the defendants do not seem to challenge that alleged misstatement on loss causation grounds.[6] Because the plaintiffs have adequately pleaded both materiality and scienter with respect to the defendants' alleged failure to disclose the impending FTC complaint and consent decree in its 2016 10-K, this claim will survive the defendants' motion to dismiss.

b. Medicare and Medicaid Exposure and 2017 Prospects

The defendants do not argue that the plaintiffs failed to allege loss causation with respect to Trudeau's alleged misstatement regarding Acthar's exposure to Medicare and Medicaid. Consequently, because the plaintiffs have adequately pleaded both materiality and scienter with respect to this alleged misstatement, this claim will survive the plaintiffs' motion to dismiss.

[6] Further, it does not appear that the defendants challenge the plaintiffs' claim of an undisclosed anticompetitive scheme on loss causation grounds, presumably because the corrective disclosure would have been the filing of the 2017 FTC complaint and consent decree. However, as the Court explained, the plaintiffs' claims with respect to Mallinckrodt's competitive positioning pertaining to Acthar will be dismissed for failure to adequately allege both materiality and scienter.

The Court agrees that the plaintiffs have failed to plead loss causation with respect to the alleged misstatement that Acthar's efficacy in its approved indications was "strongly supported by evidence." Def.'s Br. at 44–45. The plaintiffs contend that the November 2017 corrective disclosure that Acthar sales had slumped "effectively disclosed the bottom-line impact of the falsity of" the defendants' prior statement pertaining to Acthar's efficacy. Pls.' Opp'n at 64. The plaintiffs rely on the D.C. Circuit's statement in *In re Harman* that a corrective disclosure "need not be a 'mirror-image' disclosure – a direct admission that a previous statement is untrue"; it simply "must relate to the same subject matter as the alleged misrepresentation." 791 F.3d at 110 (citations omitted). At best, however, these allegations demonstrate a lack of acceptance of Acthar for some of its indications by some members of the medical community. As explained, the plaintiffs do not explain how the weaknesses in study data for certain indications concealed a risk that Acthar net sales could drop even if prescription levels increased. And the alleged November 2017 corrective disclosure that "2017 Acthar net sales would" decline, Pls.' Opp'n at 65, did not relate to the same subject matter as the critique of the scientific evidence for some of Acthar's indications. This is underscored by the fact that the medical journal and press report exposing the purported weaknesses in Mallinckrodt's data were published well after the alleged November 2017 corrective disclosure. For those reasons, the Court will dismiss the plaintiffs' complaint as it relates to the alleged misstatement that Acthar's efficacy in its approved indications was "strongly supported by evidence" for the additional reason that the plaintiffs have failed to plead loss causation.

Because the plaintiffs have adequately pleaded both materiality and scienter with respect to the remaining statements involving Mallinckrodt's 2017 prospects, and the defendants have

not challenged the remaining 2017 alleged misstatements on loss causation grounds, those claims will survive the defendants' motions to dismiss.

B. The Alleged Violation of Exchange Act Section 20(a)

In addition to their Section 10(b) claims, the plaintiffs also allege claims against Trudeau and Harbaugh under Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), for control person liability. To establish a prima facie case for control person liability under § 20(a) of the Exchange Act, a plaintiff must show (1) "a primary violation by the controlled person," and (2) "control of the primary violator by the targeted defendant." *In re Harman*, 791 F.3d at 111 (citation omitted). In their motion to dismiss, the individual defendants argue that the plaintiffs failed to plead a primary violation of the securities laws. Indiv.'s Br. at 3–10, 13–15. As discussed, the plaintiff has adequately pleaded a violation of § 10(b) with respect to several of its claimed misstatements and omissions. To the extent that those claims survive, the defendants' motion to dismiss the plaintiffs' § 20(a) claims against the individual defendants is denied.

The Court also rejects the argument that Harbaugh, Mallinckrodt's Chief Financial Officer, is not liable under § 20(a) because he merely signed the company's financial statements. *See, e.g.*, *In re Indep. Energy Holdings PLC Sec. Litig.*, 154 F. Supp. 2d 741, 767 (S.D.N.Y. 2001) (holding that false financial statements recited in a document filed with the SEC are attributable to the corporate officers that are signatories to that document); *see also Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1061 (9th Cir. 2000). Because Harbaugh signed the SEC filings that formed the basis of the plaintiffs' claims and was a high-ranking corporate officer during the Class Period, the individual defendants' motion to dismiss the claims against Harbaugh is denied to the extent that the plaintiffs' § 10(b) claims survive.

C. Leave to Amend

In their opposition, the plaintiffs request leave to amend if the defendants' motions are granted in whole or in part. Pls.' Opp'n at 67. A motion for leave to file an amended complaint must comply with Federal Rule of Civil Procedure 15(a)(2) and Local Civil Rule 15.1. "While Federal Rule 15(a) provides that leave to amend shall be freely given when justice so requires, a bare request in an opposition to a motion to dismiss—without any indication of the particular grounds on which amendment is sought—does not constitute a motion within the contemplation of Rule 15(a)." *Kowal*, 16 F.3d at 1280 (quoting *Confederate Mem'l Ass'n v. Hines*, 995 F.2d 295, 299 (D.C. Cir. 1993)) (internal quotations and alterations omitted); *see also* Local Civ. R. 15.1 (motion for leave to amend must "attach, as an exhibit, a copy of the proposed pleading as amended"). If the plaintiffs seek to amend the consolidated complaint, the plaintiffs must seek the Court's leave to amend in accordance with the Federal and Local Civil Rules.

IV. CONCLUSION

For the reasons stated above, it is **ORDERED** that the defendants' motions to dismiss are **GRANTED IN PART** and **DENIED IN PART**. Specifically, the motions are:

GRANTED with respect to the defendants' alleged failure to disclose the FTC subpoena and investigative demand in the 2014 joint proxy for failure to plead loss causation;

GRANTED with respect to the defendants' alleged failure to disclose that the sole worldwide manufacturer of Synacthen would cease manufacturing it in 2016 for failure to plead materiality, scienter, and loss causation;

GRANTED with respect to the defendants' alleged failure to disclose an unlawful antitrust scheme and their alleged misstatements about Acthar's commercial durability for failure to plead materiality and scienter;

DENIED with respect to the defendants' alleged failure to disclose the fact of an impending settlement with the FTC in Mallinckrodt's 2016 10-K;

DENIED with respect to Trudeau's alleged misstatement regarding Acthar's exposure to Medicare and Medicaid in October 2015;

DENIED with respect to the defendants' alleged misstatements and omissions in 2017 regarding the long-term prospects for Acthar's sales as far as they relate to statements about Acthar's growth across the payer mix, statements about strengthened formulary positions and the removal or relaxation of formulary restrictions, and statements conveying specific growth projections;

GRANTED with respect to the defendant's alleged misstatements and omissions in 2017 regarding the long-term prospects for Acthar's sales as far as they relate to statements about the strength of the scientific evidence supporting Acthar for failure to plead materiality, scienter, and loss causation.

DABNEY L. FRIEDRICH
United States District Judge

July 30, 2019