

I. BACKGROUND

For the purpose of this Motion to Dismiss, the Court accepts the factual allegations in the Complaint as true and draws all inferences in the light most favorable to Plaintiff. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). Further, the Court also considers any “document *integral to or explicitly relied upon* in the complaint.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

In this federal securities class action, Plaintiffs allege Novo made “a series of material misstatements and omissions about Novo’s sales of its core insulin drugs in the United States.” (Am. Compl. (ECF No. 71) ¶ 4.) Novo is a global healthcare company that derives roughly 80% of its revenue from insulin-based medications and roughly 54% of its revenue from the U.S. insulin market. (*Id.* ¶ 3.) Sorensen was Novo’s President and CEO at all times during the class period until December 31, 2016. (*Id.* ¶ 35.) Brandgaard was at all relevant times, and remains, Novo’s Executive Vice President and CFO. (*Id.* ¶ 36.) Riis² was Novo’s Executive Vice President for North America and President of Novo Nordisk Inc., Novo’s U.S. subsidiary, from September 2016 through March 2107. (*Id.* ¶ 37.) Riis was also Novo’s Executive Vice President for China, Pacific & Marketing from January 2013 to September 2016, and Novo’s Senior Vice President of Global Marketing from January 2006 through September 2016. (*Id.*) Plaintiffs bring their claims on behalf of “a proposed class of all persons and entities who purchased or otherwise acquired Novo American Depository Receipts (“ADRs”) between February 3, 2015 and February 2, 2017, inclusive (the “Class Period”).” (*Id.* ¶ 2.)

² The Court refers collectively to Sorensen, Brandgaard, and Riis as “Individual Defendants.”

A. Alleged “Kickbacks” to Pharmacy Benefit Managers (“PBMs”)

Plaintiffs contend PBMs play a significant role in the U.S. insulin market by controlling manufacturers’ ability to reach consumers. (*Id.* ¶¶ 4-5, 43-45.) Specifically, PBMs “contract with insurance companies and pharmacies, and negotiate the pricing and other terms at which prescription drugs are sold in the market.” (*Id.* ¶¶ 7, 45.) PBMs generate revenue by obtaining discounts or rebates, some of which they retain and some of which they pass on to their clients. (*Id.*) In exchange for offering rebates to PBMs, manufacturers receive access to the PBMs’ formularies, or lists of covered drugs recommended to providers. (*Id.* ¶¶ 4, 45-46.) PBMs affect the price consumers pay for drugs, the amount insurance companies cover, and whether a drug is available at all. (*Id.* ¶ 8.) Plaintiffs allege Novo and other manufacturers have such a strong incentive to remain on the formularies that they pay higher rebates to PBMs even if they must raise drug prices simply to afford the rebates. (*Id.* ¶ 45.)

Plaintiffs allege PBMs have concealed the amounts of rebates they retain, which in turn prevents insurance companies and other payors from knowing how much of a drug’s cost consists of a payment to PBMs. (*Id.* ¶ 59.) Plaintiffs contend the rebates Novo paid to PBMs are effectively “kickbacks” that inflated the price of drugs for consumers. (*Id.* ¶ 10.) Plaintiffs allege the “PBMs could use their market power to drive down the prices for insulin by forcing the drug manufacturers to compete on price for formulary placement.” (*Id.* ¶ 49.) Plaintiffs claim PBMs and insulin manufacturers, including Novo, instead “gamed the system.” (*Id.*) Plaintiffs allege Novo inflated its list prices and then paid a “kickback,” which Novo called a “rebate,” to PBMs. (*Id.*) Plaintiffs contend this was a *quid pro quo* arrangement in which PBMs received “kickbacks” and Novo received inclusion or preferential placement in formularies. (*Id.*)

B. Alleged Materially False and Misleading Statements

Several state and federal government officials have begun investigations into whether drug manufacturers' rebates to PBMs are illegal. (*Id.* ¶ 55.) Plaintiffs allege, despite these inquiries, Novo and the PBMs have concealed the details of their relationship. (*Id.* ¶ 56.) Plaintiffs contend the secrecy inherent in Novo's relationship with PBMs prevented Novo shareholders from obtaining accurate information regarding Novo's drug sales and the risk of the manufacturer meeting its financial forecasts. (*Id.* ¶ 62.)

Plaintiffs allege Novo's 2014 Annual Report misled investors by concealing the "kickbacks" to PBMs and by maintaining Novo was not subject to the pricing pressures that arose in the U.S. insulin market. (*Id.* ¶ 168-71.) Further, Plaintiffs contend the 2014 Annual Report falsely represented that a new long-acting insulin drug, Tresiba, would insulate Novo from pricing pressures. (*Id.* ¶¶ 14-15, 171.) Plaintiffs allege Novo made similar misstatements: in its First Quarter 2015 Earnings Release (*id.* ¶¶ 172-78); in its Second Quarter 2015 Earnings Release (*id.* ¶¶ 179-85); in its September 28, 2015 announcement Tresiba's FDA approval (*id.* ¶¶ 186-93); during its November 19, 2015 Capital Markets Day (*id.* ¶¶ 194-95); in its Fourth Quarter and Full-Year 2015 Earnings Releases (*id.* ¶¶ 196-210); in its First Quarter 2016 Earnings Release (*id.* ¶¶ 211-17); in its Second Quarter 2016 Earnings Release (*id.* ¶¶ 218-22); and in its Third Quarter 2016 Earnings Release (*id.* ¶¶ 223-27).

1. Statements About Reasons for and Sustainability of Novo's Growth

Plaintiffs allege Novo misled investors by touting its sales, earnings, and forecasts without disclosing the role payments to PBMs played in Novo's past and future success. (*Id.* ¶ 79.) Plaintiffs contend Novo's April 30, 2015 Form 6-K, filed with the SEC, stated: "Sales of insulin increased by 22% . . . sales growth was driven by North America." (*Id.* ¶ 80.) Plaintiffs allege

Novo made similar statements throughout the Class Period, despite the fact Novo's reported sales, earnings, and forecasts were unsustainable and unachievable because of the role of payments to PBMs. (*Id.* ¶¶ 80-81.) Plaintiffs claim Novo failed to make required SEC disclosures regarding the effect of PBM rebates on Novo's revenues and operating profit. (*Id.* ¶ 82.) In Novo's 2015 Annual Report, the company stated its "[p]roduct success is largely based on competition on efficacy, safety, quality and price." (*Id.* ¶ 83.) Plaintiffs contend this statement was misleading because Defendants knew PBMs based their selections of insulin drugs on rebate payments, not those criteria. (*Id.*)

In an article in *Bloomberg* published on November 11, 2016, Sorensen claimed Novo raised prices to compensate for increased rebates to PBMs. (*Id.* ¶ 87.) On November 30, 2016, Novo posted a statement on its website stating, while it sets a "list price" for drugs, the price or profits Novo receives is calculated after "rebates, fees and other price concessions [it] provide[s] to the payer." (*Id.* ¶ 88.) On May 10, 2017, Novo's new CEO Lars Jorgensen ("Jorgensen") stated in an interview with *Bloomberg* that drug efficacy had not determined drug price. (*Id.* ¶ 89.) Plaintiffs allege these statements reveal Defendants admitted the *quid pro quo* arrangement with PBMs, not the efficacy of Novo's products, determined prices. (*Id.* ¶¶ 88-89.)

2. Novo's Denials It Was Subject to Pricing Pressures of U.S. Insulin Market

Plaintiffs allege, prior to the Class Period, Novo's competitors reported pricing pressures from the PBM rebates had begun to have a negative impact. (*Id.* ¶ 90.) During an October 28, 2014 conference call with investors, Sanofi S.A. ("Sanofi") reported lower-than-expected earnings growth it attributed to "competitive pressure at the payor level." (*Id.*) Plaintiffs contend Novo was subject to these same pressures but failed to inform investors and instead reassured investors Novo's earnings were not at risk. (*Id.* ¶ 91.) On February 3, 2015, Novo held an earnings

conference call in which an analyst from Mitsubishi Financial Group asked why Novo claimed it did not see problems due to U.S. pricing even though its competitors reported the outlook was “terrible.” (*Id.* ¶ 92.) In response, Sorensen and Novo’s then-President and COO Kare Schultz denied competitive pressures would have an impact and predicted a “pretty stable situation for 2015.” (*Id.*) On an April 30, 2015 conference call, Sanofi again told investors increased rebates would negatively affect revenue despite increased sales of its drug Lantus. (*Id.* ¶ 95.) On the same day, on an earnings call, Sorensen told investors, “We are not anticipating any pricing impact in 2015.” (*Id.* ¶ 96.) Analysts responded to Novo’s statements by reporting a positive outlook for the company. (*Id.* ¶ 97.) Plaintiffs allege Novo made similar misrepresentations about the lack of effect pricing pressures would have on the company throughout the remainder of the Class Period. (*Id.* ¶¶ 98-110.) Plaintiffs further allege two independent witnesses³ claim Jesper Hoiland (“Hoiland”), Novo’s former President of U.S. operations, told the company’s executive management and the Board of Directors in early 2015 and throughout the Class Period that increased pricing pressures in the U.S. would prevent Novo from meeting its U.S. growth targets. (*Id.* ¶ 110.) Plaintiffs contend Defendants ignored these warnings and misrepresented Novo’s ability to withstand increased pricing pressures. (*Id.* ¶ 110.)

3. Novo’s Alleged False Representations Regarding Tresiba

Plaintiffs allege Novo falsely claimed throughout the Class Period that Tresiba would insulate the company from pricing pressures affecting Novo’s competitors in the U.S. market. (*Id.* ¶ 111.) Plaintiffs contend Novo represented Tresiba as an innovative drug, superior to competing products, despite the fact it knew Tresiba was virtually the same as insulin drugs already on the

³ The witnesses are Brian Lundstrom (“Lundstrom”), who was a Novo investor, and an anonymous Vice President of Diabetes Marketing in the U.S. for Novo (the “Marketing VP”). (ECF No. 71 ¶¶ 21, 23, 110.)

market. (*Id.*) Plaintiffs claim, in 2015 and 2016, senior Novo executives in the U.S. warned the Individual Defendants that Tresiba would not boost earnings in the U.S. due to (1) pricing pressures and (2) the fact that they could not substantiate premium pricing for the product. (*Id.*) Plaintiffs allege, in 2014, the German Institute for Quality and Efficiency in Health Care found Tresiba showed “no added benefit” over existing insulin drugs on the market. (*Id.* ¶ 112.) Plaintiffs further allege, in the summer of 2015, the relevant German authority prohibited Novo from charging premium pricing for Tresiba in Germany. (*Id.*) Plaintiffs contend France also rejected Novo’s claim that Tresiba was an improvement over insulin products on the market. (*Id.* ¶ 113.)

Plaintiffs allege, despite Novo’s knowledge that Tresiba was not an improvement over existing products, the company stated in an April 30, 2015 earnings call that Tresiba would allow the company “to achieve 10% or more top-line growth in the diabetes market.” (*Id.* ¶ 115.) During a September 28, 2015 conference call about Tresiba’s FDA approval, Novo stated Tresiba was superior to competing products and would “warrant a modest premium” in price. (*Id.*) Plaintiffs allege Novo made numerous similar statements about Tresiba throughout the rest of 2015 and as recently as May 2016. (*Id.*) Plaintiffs contend Novo’s statements about Tresiba led analysts, including Morningstar, Barclays, and Morgan Stanley, to report the product would allow Novo to reach its long-term targets. (*Id.* ¶ 116.) Plaintiffs allege Tresiba proved to be a disappointment that could not support Novo’s projected profit growth. (*Id.* ¶ 118.)

C. Corrective Disclosures and Effects on the ADR Price

Plaintiffs claim, as the Class Period progressed, prices of Novo’s insulin products and those of its competitors rose and became unaffordable for many patients. (*Id.* ¶ 119.) Plaintiffs contend pricing pressures and increased scrutiny of insulin prices forced Novo to acknowledge a decline in earnings. (*Id.* ¶ 123.) Plaintiffs allege, on August 5, 2016, Novo announced its earnings for the

first six months of 2016 were disappointing due in part to “a challenging pricing environment especially in the basal insulin” segment. (*Id.*) Novo adjusted its forecasts for growth for the year to 5-7%, down from 5-9%. (*Id.*) Plaintiffs allege Novo was forced to make a series of corrective disclosures, which led Novo ADRs to decline from a price of \$55.20 per ADR on August 4, 2016, the day before the first disclosure, to \$33.48 per ADR at the close of the Class Period. (*Id.* ¶¶ 24, 127.) On September 1, 2016, Novo announced Sorensen would leave the company at the end of 2016, despite a previous announcement, on April 30, 2015, that he would remain with Novo until 2019. Also on September 1, 2015, Novo announced Hoiland and several other senior executives were leaving the company. (*Id.*)

D. Alleged Evidence of Scienter

Plaintiffs allege Hoiland told Lundstrom he and Sorensen were fired, contrary to Novo’s public claim that the departures were voluntary. (*Id.* ¶ 149.) Plaintiffs further allege the Marketing VP and other former Novo employees claim Defendants’ statements during the Class Period were false and misleading, and that Defendants knew or recklessly disregarded the falsity of their statements. (*Id.* ¶ 152.) Plaintiffs claim the former employees’ allegations support a strong inference of scienter. (*Id.*) Plaintiffs allege the Individual Defendants confirmed on earnings calls during the Class Period they were personally involved with setting prices and negotiating PBM contracts. (*Id.* ¶ 243.) Plaintiffs contend this is additional evidence of scienter, because Novo’s dealings with PBMs, its statements about U.S. pricing and growth, and its representations about Tresiba on the earnings calls were the basis of Defendants’ misstatements and omissions. (*Id.*) Plaintiffs allege additional evidence of scienter can be found in the fact Sorensen and Brandgaard signed Sarbanes-Oxley certifications that “they personally supervised and participated in the evaluation of Novo’s financial controls and procedure, and that [Novo]’s financial disclosures

fairly and accurately presented its financial condition. (*Id.* ¶ 244) Finally, Plaintiffs allege an inference of scienter can be drawn from Novo's compensation structure. (*Id.* ¶ 247.) Plaintiffs contend the compensation structure, which allowed some executives to nearly double their compensation through receipt of shares, incentivized fraud. (*Id.* ¶¶ 248-50.)

E. The Statutory Safe Harbor

Plaintiffs argue none of the false and misleading statements in the Amended Complaint were forward-looking, and therefore do not fall in the statutory safe harbor. (*Id.* ¶ 272.) Plaintiffs further posit, to the extent any statements were forward-looking, they were not accompanied by meaningful cautionary language identifying facts that could cause results to differ materially from the statements. (*Id.* ¶ 274.)

F. Procedural Background

Following the Court's consolidation of related cases (ECF No. 42), Plaintiffs filed the Amended Complaint on August 4, 2017. (ECF No. 71.) Plaintiffs assert claims for (1) violations of Section 10(b) and Rule 10b-5 of the Exchange Act against all Defendants (Count I), and (2) violations of Section 20(a) of the Exchange Act against Individual Defendants (Count II). Defendants' Motion to Dismiss followed. (ECF No. 81.) On July 25, 2018, the Court heard oral argument on this motion.⁴

⁴ On July 31, 2018, and August 1, 2018, respectively, Plaintiffs and Defendants filed letters regarding this Court's recent decision in *Roofer's Pension Fund v. Papa*, No. 16-2805, 2018 WL 3601229, *1 (D.N.J. July 27, 2018), in which the Hon. Madeline Cox Arleo, U.S.D.J. denied the defendants' motion to dismiss plaintiffs' claims under Section 10(b) of the Exchange Act. (ECF Nos. 97 and 98.) Judge Arleo ruled plaintiffs adequately alleged defendants made material misstatements when they knowingly overstated the value of a royalty stream. *Roofer's Pension Fund*, 2018 WL 3601229 at *9. The Court considered these submissions and determined Judge Arleo's opinion is limited to the specific facts of *Roofer's Pension Fund*.

II. LEGAL STANDARD

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is “required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff].” *Phillips*, 515 F.3d at 228. “[A] complaint attacked by a . . . motion to dismiss does not need detailed factual allegations.” *Bell Atl. v. Twombly*, 550 U.S. 544, 555 (2007). However, the Plaintiff’s “obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is “not bound to accept as true a legal conclusion couched as a factual allegation.” *Papasan*, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555.

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 570). “A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged.” *Id.* This “plausibility standard” requires the complaint allege “more than a sheer possibility that a defendant has acted unlawfully,” but it “is not akin to a ‘probability requirement.’” *Id.* (quoting *Twombly*, 550 U.S. at 556). “Detailed factual allegations” are not required, but “more than an unadorned, the defendant-harmed-me accusation” must be pled; it must include “factual enhancements” and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citing *Twombly*, 550 U.S. at 555, 557).

“Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 679. “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]’—‘that the pleader is entitled to relief.’” *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

While as a general rule, a court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to 12(b)(6), the Third Circuit has held “a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant under Rule 56].” *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any “document *integral to or explicitly relied upon* in the complaint.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426.

III. DECISION

To state a claim for securities fraud pursuant to Section 10(b) of the Exchange Act, “plaintiffs must allege (1) a material misrepresentation or omission, (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.” *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014) (citations omitted). A “securities fraud claim is subject to the heightened pleading requirements” of Federal Rule of Civil Procedure 9(b). *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 236 (3d Cir. 2004). The PSLRA, 15 U.S.C. § 78u, “‘imposes another layer of factual particularity to allegations of securities fraud.’” *Id.* at 236-37 (quoting *In re Rockefeller*, 311 F.3d at 217). Pursuant to the PSLRA, the complaint shall 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, the complaint shall state with particularity all facts on which that belief is formed.” *Id.* at 237 (quoting 15 U.S.C. § 78u4(b)(1)).

Here, Defendants challenge only two elements of Plaintiffs’ claims, namely whether the statements Defendants made were false or misleading, and whether Plaintiffs sufficiently alleged scienter on the part of Defendants. (Ds.’ Br. in Supp. of the Mot. for Summ. J. (ECF No. 81-1).) Defendants do not contest the materiality of the alleged misstatements. (*Id.*) Defendants argue Plaintiffs’ claims should be dismissed because: (1) Plaintiffs fail to plead a material misstatement or omission; (2) the SEC Bulletin and Releases cited in the Amended Complaint did not create a disclosure obligation and cannot give rise to liability; (3) Plaintiffs fail to plead particular facts giving rise to an inference of scienter; and (4) Novo’s forward-looking statements and its statements of opinion are immunized by the PSLRA. (*Id.*) The Court considers these arguments in turn.

A. Alleged Material Misstatements and Omissions

Defendants argue, contrary to Plaintiffs’ claims, Novo publicly disclosed the impact of PBM rebates and increased pricing pressures during the Class Period. (*Id.* at 6.) Defendants point to statements in Novo’s 2014 Annual Report, which stated PBMs “widely used . . . tightly controlled Preferred Drug Lists” and asserted “rebate negotiations have become tougher for the pharmaceutical industry.” (*Id.* (quoting 2014 Annual Report (ECF No. 81-3) at 23.) The 2014 report also predicted “the US price environment [would] become more challenging.” (*Id.*) Defendants also point to similar statements regarding rebate negotiations in Novo’s 2015 Annual Report. (ECF No. 81-14 at 36-37.) Defendants contend Plaintiffs themselves acknowledge in the

Amended Complaint that “the role of rebates in the pharmaceutical market was ‘well-known.’” (ECF No. 81-1 at 22 (quoting ECF No. 71 ¶ 46).)

Defendants argue Plaintiffs have failed to identify a material misstatement or omission regarding Tresiba. (*Id.* at 25.) They contend, rather than promise investors Tresiba would insulate Novo from pricing pressures, Novo warned investors the company would pursue a long-term market access strategy. (*Id.* at 26 (citing FQ3 2015 Earnings Call Transcripts (ECF No. 81-9) at 12-13).) Defendants maintain the statements Plaintiffs allege were misrepresentations were both forward-looking and statements of opinion. (*Id.* (citing ECF No. 71 ¶¶ 62, 210).)

Plaintiffs counter by arguing Defendants violated the Exchange Act not by concealing and misrepresenting rebates to PBMs, but by falsely attributing Novo’s success to the strength of its products rather than the rebates paid. (ECF No. 87 at 18.) Plaintiffs contend Defendants had a duty to refrain from misleading investors. (*Id.* at 19 (citing *Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1098 n.7 (1991)).) Similarly, Plaintiffs argue Defendants made materially false and misleading statements and omissions about Novo’s vulnerability to pricing pressures. (*Id.* at 21 (citing ECF No. 71 ¶¶ 90-109).) Finally, Plaintiffs claim Defendants effectively claimed Tresiba would insulate Novo from market dynamics. (*Id.* at 27 (citing ECF No. 71 ¶¶ 192, 216).)

The Court finds Plaintiffs have adequately alleged Defendants made material misstatements and omissions. Plaintiffs cite numerous specific statements in which Defendants attributed Novo’s success to the efficacy of its products (*see, e.g.*, ECF No. 71 ¶¶ 83, 208) only to later admit PBM rebates were key to ensure Novo’s products were included on preferred drug formularies (*id.* ¶ 88). Plaintiffs also cite several statements in which Defendants assured investors Novo’s growth would continue despite increasing pressures in the market. (*See, e.g.*, ECF No. 71 ¶¶ 106-09.) While Defendants cite statements in Novo’s 2014 and 2015 Annual Reports in which

the company acknowledged PBMs and the challenges of the pricing environment in the U.S. market, these disclosures do not preclude the possibility Defendants' statements were misleading. *See Edinburgh Council*, 754 F.3d at 171 (finding allegedly misleading statements must be read in context of the documents in which they appear). Despite Defendants' statements acknowledging the challenges of PBM contracts and pricing pressures in the market, the Court finds Plaintiffs have adequately alleged shareholders were misled by Defendants' contrary statements. *See Va. Bankshares*, 501 U.S. at 1097 (“[N]ot every mixture with the true will neutralize the deceptive.”).

As to Defendants' statements regarding Tresiba, the Court finds Plaintiffs adequately pled those statements were misleading. Plaintiffs point out German and French regulators rejected Novo's claims that Tresiba was superior to other insulins. (ECF No. 71 ¶¶ 112-13.) Further, at oral argument, counsel for Plaintiffs noted the Amended Complaint alleges market analysts credited Novo's statements about Tresiba's quality and ability to contribute to the company's growth. (*See id.* ¶¶ 101-03.) After Novo's stock price dropped, analysts attributed Novo's more negative projected growth, in part, to Tresiba's failure to live up to the company's assertions about its quality. (*Id.* ¶ 140.)

Therefore, the Court finds Plaintiffs have sufficiently pled Defendants made materially misleading statements as to PBM rebates and the pricing pressures in the U.S. Market and regarding Tresiba.

B. SEC Accounting Bulletin No. 104 (“SAB 104”)

SAB 104 provides guidance to companies regarding disclosures related to changes in revenue. (ECF No. 71 ¶ 229.) In their briefs, the parties agree the duty to disclose under SAB 104 is not a basis for liability on its own. (ECF No. 87 at 28; ECF No. 91 at 11.) Plaintiffs argue a violation of SAB 104's duty to disclose can serve as evidence of liability under Section 10(b).

(ECF No. 87 at 28.) In response, Defendants argue Novo’s disclosures throughout the Class Period complied with SAB 104’s requirements. (ECF No. 91 at 11.)

As the parties agree Defendants’ compliance with SAB 104 is not a basis for liability, but potentially evidence of liability, the Court need not address this question on a motion to dismiss. SEC bulletins can provide “persuasive guidance for evaluating . . . an alleged” securities violation. *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 163 (2d Cir. 2000). The Court has already found Plaintiffs have adequately alleged Defendants made material misstatements. Therefore, the issue of Defendants’ compliance with SAB 104’s requirements is not material to this Motion to Dismiss.

C. Facts Supporting an Inference of Scienter

“[P]laintiffs may establish a ‘strong inference’ that the defendants acted with ‘scienter’ ‘either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.’” *GSC Partners*, 368 F.3d at 237 (quoting *In re Burlington*, 114 F.3d at 1418). Plaintiffs must support their allegations of motive with facts stated with particularity. *Id.* Plaintiffs cannot merely plead defendants had a motive “generally possessed by most corporate directors and officers,” but “must assert a concrete and personal benefit to the individual defendants resulting from [the alleged] fraud.” *Id.* (quoting *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001)). If plaintiffs cannot adequately plead motive, they must “allege specific facts that constitute ‘strong circumstantial evidence of conscious misbehavior or recklessness.’” *Id.* at 238 (quoting *Oran v. Stafford*, 226 F.3d 275, 288-89 (3d Cir. 2000)). “The inquiry is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007). To survive a motion to dismiss, plaintiffs must plead

facts that allow “a reasonable person [to] deem the inference of scienter cogent and at least as compelling as any plausible opposing inference once could draw from the facts alleged.” *Id.*

Here, Defendants argue Plaintiffs have failed to plead scienter because the Amended Complaint relies on (1) witness and confidential informant accounts that lack the required specificity, and (2) boilerplate allegations that courts routinely reject. (ECF No. 91 at 11.) The Court disagrees and finds Plaintiffs have sufficiently pled facts that support a strong inference of scienter.

1. Witness Accounts

The Amended Complaint includes numerous allegations by witnesses, including Lundstrom. (ECF No. 71 ¶¶ 147-57.) Lundstrom claims Hoiland told him he warned Novo’s senior management throughout the class period that Novo would not meet its long-term growth targets because of pricing pressure in the U.S. market. (*Id.* ¶ 22.) The Amended Complaint also alleges Hoiland and Novo’s senior executives discussed the unsustainability of Novo’s financial forecasts as early as 2015. (*Id.* ¶ 149.) At oral argument and in their motion papers, Defendants argued Lundstrom’s accounts of what Hoiland told him about Hoiland’s interactions with Novo management are hearsay and therefore of no probative value. But the Third Circuit has held witness accounts in a complaint must only include “sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.” *Cal. Pub. Emps.’ Ret. Sys v. Chubb Corp.*, 394 F.3d 126, 143 (quoting *Novak v. Kasaks*, 216 F.3d 300, 313-14 (2d Cir. 2000)). The Court finds the witness accounts in the Amended Complaint satisfy that standard.

2. Plaintiffs' Additional Allegations Support Scienter

Plaintiffs argue the Court can draw an inference of scienter from the fact that Defendants' alleged misstatements concerned Novo's core business—insulin drugs. (ECF No. 87 at 33 (citing *In re Cell Pathways, Inc.*, 2000 WL 805221, at *7 (E.D. Pa. June 20, 2000) (finding “where the alleged fraud relates to the core business of the company, knowledge of the fraud may be imputed to the individual defendants”))). Plaintiffs rely on *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242 (3d Cir. 2009), in which the shareholder plaintiffs alleged the defendant company (1) falsely denied it was offering price discounts due to increased pricing pressure and (2) released false or misleading financial projections. (ECF No. 87 at 34 (citing 564 F.3d at 247-49).) Plaintiffs argue *Avaya* controls, because the Third Circuit held the plaintiffs adequately pled scienter when the defendant chief financial officer denied the company's pricing would change after analysts asked about the issue repeatedly. (*Id.* (citing 564 F.3d at 269-70).)

Plaintiffs' additional evidence of scienter—Novo's share-based compensation structure (ECF No. 71 ¶¶ 247-51) and Sorensen's and Hoiland's departure (*id.* ¶¶ 252-53)—contribute to a finding of scienter. While these individual allegations may not give rise to an inference of scienter on their own, “all of the facts alleged, taken collectively, give rise to a strong inference of scienter.” *Tellabs, Inc.*, 551 U.S. at 310. Accordingly, the Court finds Plaintiffs have adequately alleged scienter.

D. Safe Harbor

The PSLRA's safe harbor provision “immunizes from liability any forward-looking statement, provided that: the statement is identified as such and accompanied by meaningful cautionary language; or is immaterial; or the plaintiff fails to show the statement was made with actual knowledge of its falsehood.” *Avaya*, 564 F.3d at 254 (citing 15 U.S.C. § 78u-5(c)).

The term “forward-looking statement” is broadly defined in the statute to include statements “containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items”; statements of “the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer”; or statements of “future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission.” 15 U.S.C. § 78u-5(i)(1)(A)-(C). Further, forward-looking statements include “any statement of the assumptions underlying or relating to any statement described” in the definition. § 78u-5(i)(1)(D).

Id. at 255. Mixed present and future statements are entitled to the safe harbor only as to the portion of the statement that refers to the future. *Id.* (citations omitted).

Plaintiffs allege the safe harbor should not apply because Defendants did not make forward-looking statements, but “historical statements of purportedly current facts and conditions at the time the statements were made, including statements about pricing pressures that Novo and its competitors faced.” (ECF No. 71 ¶ 273.) Plaintiffs contend, to the extent Defendants’ statements were forward-looking, the statements were not accompanied by meaningful cautionary language identifying important facts that could cause results to differ materially from the statements. (*Id.* ¶ 274.) Plaintiffs argue, even if the safe harbor were to apply, Defendants are nonetheless liable because they were aware the statements were materially false or misleading at the time they made them. (*Id.* ¶ 275.) Plaintiffs identify two categories of statements in which the safe harbor should not apply: (1) claims related to Tresiba’s expected performance, and (2) Novo’s projections regarding targets and pricing. (ECF No. 87 at 28-31.)

1. Forward-looking statements about Tresiba

The Amended Complaint cites several statements regarding Tresiba. On an April 30, 2015 earnings call, Sorensen stated, “Basically, it’s our anticipation that if and when we get approval

for Tresiba in the US and when we are able to launch the degludec family in the US, that will allow us to achieve 100% or more top-line growth in the diabetes market.” (ECF No. 71 ¶ 176.) Plaintiffs also cite Defendants’ statement, “[W]e do believe the product itself warrants a premium price.” (*Id.* ¶ 186.) Defendants also stated in regard to Tresiba, “[W]e believe that we are well positioned to . . . pursue the high end of the market, based on innovation.” (*Id.* ¶ 194.) Plaintiffs argue these statements do not fall within the safe harbor because were based on misrepresented present facts. (ECF No. 87 at 29.) Plaintiffs contend Defendants knew at the time of those statements that German and French authorities found Tresiba was substantially similar to existing drugs and therefore did not warrant a premium price. (*Id.* at 25, 29.)

The Court agrees. Plaintiffs have sufficiently alleged Defendants were aware of negative issues related to Tresiba at the time they made statements about the drug’s efficacy. (ECF No. 71 ¶¶ 176, 186, 191.) While portions of Defendants’ statements about Tresiba were forward looking, those elements were made in conjunction with present representations about the drug. *See Avaya*, 564 F.3d at 255. While Defendants acknowledged the negative developments in the German and French markets (ECF No. 91 at 9), the “cautionary language must be extensive yet specific and touch upon the subject matter of the alleged misrepresentation in order for the safe harbor to apply.” *In re: Enzymotec Secs. Litig.*, No. 14-5556, 2015 WL 8784065, at *7 (D.N.J. Dec. 15, 2015) (citing *Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000)). The Court finds the disclosures upon which Defendants rely were not adequate, particularly in light of the strong positive statements Novo made concerning Tresiba.

2. Projections Regarding Targets & Pricing

Plaintiffs also allege Defendants stated on an August 6, 2015 earnings call that insulin prices would be “from flat to slight positive pricing.” (ECF No. 71 ¶ 183.) While this is a statement

regarding a future occurrence, Plaintiffs allege Defendants based the statement on a representation of present fact, namely that Defendants had entered into contracts that gave them “the price picture” for the coming year. (*Id.*) Plaintiffs argue Defendants later acknowledged that statement was false when Novo stated “contract negotiations for 2017 resulted in higher-than-anticipated rebates to obtain broader coverage for our products.” (*Id.* ¶ 158.) The Court agrees and finds Plaintiffs have sufficiently alleged Defendants made material misstatements that were not merely forward looking and are not protected by the safe harbor.

Therefore, the Court finds Defendants’ statements do not fall within the PSLRA’s safe harbor, and Plaintiffs have adequately alleged Defendants made material misstatements in violation of the Exchange Act.

IV. CONCLUSION

For the reasons set forth above, Defendants’ Motion to Dismiss (ECF No. 81) is **DENIED**. An appropriate Order will follow.

Date: August 16, 2018

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE