SEEGER WEISS LLP
CHRISTOPHER A. SEEGER
DAVID R. BUCHANAN
550 Broad Street, Suite 920
Newark, NJ 07102
Telephone: 973/639-9100
973/639-9393 (fax)

CARELLA, BYRNE, CECCHI, OLSTEIN,
BRODY & AGNELLO, P.C.
JAMES E. CECCHI
5 Becker Farm Road
Roseland, NJ 07068
Telephone: 973/994-1700
973/994-1744 (fax)

Co-Liaison Counsel and Executive Committee Members for the Class

[Additional counsel appear on signature page.]

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

In re NOVO NORDISK SECURITIES LITIGATION	Master File No. 3:17-cv-00209-BRM-LHG
This Document Relates To: ALL ACTIONS.	CLASS ACTION

LEAD PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CLASS ACTION COMPLAINT

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Co-Lead Plaintiffs Central States, Southeast and Southwest Areas Pension Fund, Lehigh County Employees' Retirement System, Oklahoma Firefighters Pension and Retirement System, Boston Retirement System, and Employees' Pension Plan of the City of Clearwater ("Plaintiffs") respectfully submit this memorandum of law in opposition to Defendants' Motion to Dismiss Plaintiffs' Consolidated Amended Class Action Complaint (ECF No. 81) (the "Motion").[1]

I. PRELIMINARY STATEMENT

Throughout the Class Period, Defendant Novo Nordisk A/S ("Novo" or the "Company") and its senior executives repeatedly told investors that the Company would succeed over its competitors in the U.S. market because Novo had "***a very strong position with a gold standard product***," which supported higher pricing and formulary placement. As Defendants knew, those statements were false.

The U.S. insulin market is dominated by three companies: Novo, Sanofi, and Eli Lilly. Each sells comparable drugs to the same pool of diabetes patients. In order to get their insulin drugs in patients' hands, Novo, Sanofi, and Eli Lilly must first strike deals with pharmacy benefit managers ("PBMs"), who are middlemen that negotiate drug pricing on behalf of insurance companies, pharmacies, and other

[1] Unless otherwise specified, all references to "¶ __" are to paragraphs of the Consolidated Amended Class Action Complaint (ECF No. 71) (the "Complaint"); references to "D. Br." are to Defendants' memorandum of law in support of the Motion (ECF No. 81-1); all defined terms have the meanings assigned in the Complaint; and all emphasis in quoted material is added.

buyers. PBMs are gatekeepers to the formularies and preferred-drug lists that dictate whether insurance will cover a specific drug and, as a result, whether a market exists for the drug. PBMs profit from the size of rebates paid by drugmakers to offset their drugs' list prices. Thus, contrary to Novo's statements, Novo and its competitors fought for market share by offering higher and higher rebates to the PBMs, regardless of how high they had to raise list prices to support those ever-larger rebates. The drugs did not compete on price or efficacy.

Although investors knew that Novo's relationships with PBMs included rebate payments, investors did not know (a) the amount of the rebates paid, (b) whether those rebate payments were sustainable, or (c) that Novo's market access was wholly dependent on its ability to continue raising prices in order to pay larger and larger rebates. Rather, investors credited what Defendants repeatedly told them: "***[p]roduct success [in the United States] is largely based on competition on efficacy, safety, quality and price***," Novo "has been able to maintain the leading position in the overall diabetes care market through the ***quality and innovative value of the company's diabetes care products***," and Novo had leverage based on its products' strength, so that "we do compete, but ***we make our own decisions***."

List prices and rebates could not continue rising indefinitely. Eventually, purchasers who did pay list price, including patients enrolled in high-deductible health plans who bore the full cost of their insulin drugs, balked at skyrocketing

prices, drawing a public outcry and multiple government investigations. Beginning prior to the Class Period, Sanofi and Eli Lilly reduced their earnings guidance, attributing the lower expectations to both large rebates for formulary access and pricing pressures that prevented further list-price hikes. But Novo steadfastly claimed that it was positioned better, including because its new drug, Tresiba, would soon hit the U.S. market and command premium pricing, thereby protecting Novo from the pressures affecting its competitors. Novo told investors that its financial results had "***nothing to do with competition***," it had full visibility and would be able to maintain market share "***based on the portfolio we have***," and Novo's products allowed it to "***make our own decisions***."

Defendants further told investors that Tresiba was an "***innovative product***" that it could sell "***at a high price***" and therefore "***uphold the value of all our portfolio***." Defendants represented to investors that Tresiba "***will allow us to achieve 10% or more top-line growth in the diabetes market***" so that Novo "***will be pushing products up based on innovation***." Those statements were false. As Defendants knew from the decisions of German and French regulators, the quality of Novo's products – including Tresiba – did not sufficiently differentiate Novo from its competitors. Indeed, PBMs granted Novo formulary access not because of differences in its product quality, but instead based on its willingness to pay increasingly high rebates, as the PBMs knew that the insulin drugs on the market –

including the newly launched Tresiba – were substantially similar and thus interchangeable, despite Novo's claims to the contrary. Senior executives repeatedly warned the Company's top management, including the Individual Defendants,[2] that the Company's drug portfolio could not sustain reported growth and guidance, and that Tresiba did not justify premium pricing. The truth finally emerged because Novo had no choice but to report lower earnings and slash its guidance, and Novo's securities plummeted in value. As a result, investors suffered substantial harm.

In their Motion, Defendants misconstrue the allegations in the Complaint: that, given Defendants' knowledge that Novo's product portfolio did not differentiate the Company from its competitors, and the PBMs' focus on rebate size, Novo faced the same pricing pressures as its competitors, and Defendants' repeated assurances that its products supported sustained earnings and growth were thus materially false and misleading. Defendants do not, and cannot, credibly dispute that they misled investors about the primary reason for Novo's products' inclusion on formularies, the sustainability of growing rebates to PBMs, Novo's exposure to pricing pressures, or whether Tresiba justified premium pricing – the truth of all of

[2] The Individual Defendants are Novo's President and Chief Executive Officer throughout the Class Period, Lars Rebien Sørensen; Novo's Executive Vice President and Chief Financial Officer, Jesper Brandgaard; and Novo's Senior Vice President for Global Marketing throughout the Class Period and, later, Executive Vice President for North America and President of Novo's U.S. subsidiary Novo Nordisk, Inc., Jakob Riis.

which the Individual Defendants knew at the time. As discussed below, and because Defendants' arguments are meritless, the Court should deny Defendants' Motion and sustain Plaintiff's well-pled Complaint.

II. FACTUAL BACKGROUND

A. Pharmacy Benefit Managers Control Access to the U.S. Insulin Market, Novo's Main Revenue Driver

Novo is a global drug company that derives 80% of its revenue from insulin drugs. ¶ 3. Insulin sales in the U.S. market represented 54% of Novo's revenues between 2012 and 2016, and are the primary driver of Novo's financial results. ¶¶ 3, 40, 42. Although Novo and its competitors set list prices for their insulin drugs, customers – primarily PBMs – rarely pay that amount, and instead negotiate for significant rebates and discounts from the pharmaceutical companies. ¶¶ 43-45. In exchange, PBMs provide access to their preferred-drug lists and formularies – through which Novo's and its competitors' drugs are made available to individual consumers. *Id*.

Although drug makers' list prices are public, the amounts of discounts and rebates to customers are closely guarded secrets. For example, the Chief Medical Officer of PBM Express Scripts has stated that "what we don't want is transparency" (¶ 59); PBM CVS Health's President and CEO likewise referred to pricing specifics as "our secret sauce" (¶ 46). Without knowing the size of rebates Novo provided to PBMs or the behind-the-scenes truth, investors could not determine (1) whether the

rebates grew larger in order to keep Novo's drugs on formularies; (2) whether certain trends were occurring, such as PBMs increasing rebate requirements, that directly and materially impacted Novo's profits; and (3) whether Novo could continue to grow earnings and market share. ¶ 62.

B. The Kickback Scheme in the U.S. Insulin Market

The U.S. insulin market is highly concentrated, with the market largely split between Novo (37%), Sanofi (37%), and Eli Lilly (24%). ¶¶ 40, 73. Novo and its competitors manufacture name-brand insulin drugs in a variety of drug classes, but the drugs are "commoditized." In other words, the manufacturers' drugs within each class are substantially similar such that patients may switch from one company's medication to another, frequently with only a pharmacist's approval and no need for a doctor's prescription. ¶¶ 13, 77.

Contrary to Defendants' claims, Novo and its competitors did not compete on drug quality and performance, but by offering ever-increasing rebates to PBMs. ¶¶ 48-49. Prior to and during the Class Period, in order to ensure formulary access, Novo and the other manufacturers repeatedly raised their list prices, only to then increase the kickbacks to PBMs, which they misleadingly called "rebates," off the list prices. ¶ 49. For a time, that *quid pro quo* benefitted the insulin manufacturers and the PBMs. ¶ 50. In the first year of the Class Period, CVS Health reported more than $100 billion in revenues due to "favorable . . . rebate economics." ¶ 54.

Novo and its competitors consistently raised their drug prices in lockstep. For example, the list prices of Novo's and Eli Lilly's fast-acting insulin pens were raised from just under $15 to nearly $40 between February 2009 and October 2016, with a 99.9% correlation in prices. ¶¶ 67-68, 70-71. Meanwhile, the prices of Novo's and Sanofi's long-acting insulin pens nearly doubled between 2012 and 2016, with a 98.7% price correlation. ¶¶ 69-71. Such lockstep increases, without any economic or commercial justification, eventually caught the attention of regulators and key interest groups. On November 3, 2016, Sen. Bernie Sanders and Rep. Elijah Cummings called on the Department of Justice to probe collusion between insulin makers and, two weeks later, the American Diabetes Association asked Congress for "hearings to investigate dramatic increases in insulin prices and to take action to ensure that people have affordable access to the essential drug." ¶¶ 141-42.

C. Pricing Pressures Erode Earnings of the Insulin Manufacturers

Prior to and throughout the Class Period, pricing pressures in the U.S. insulin market materially eroded the financial results of Novo and its competitors, spurred on by the ever-rising list prices and rebates discussed above. ¶¶ 90, 119. Novo's competitors publicly acknowledged these pricing pressures and their impact on earnings. For example, for 3Q 2014, Sanofi reported lower-than-expected growth due to "increased competitive pressure at the payor level," explaining that "[t]he level of rebates required to maintain these positions has increased significantly."

¶ 90. Throughout 2015, Novo's competitors disclosed, among other things, that "increased rebates from most contracts . . . were required to secure favorable formulary position"; that they were seeing "continued pricing impact"; and that they were expecting "further price erosion." ¶¶ 95, 99, 100.

D. Novo Falsely Denied Its Exposure to Pricing Pressures

Throughout the Class Period, Defendants consistently and expressly denied that the market pressures that competitors reported were negatively affecting Novo. For example, on February 3, 2015, the first day of the Class Period, Novo's then-President Kåre Schultz publicly rejected "the widespread notion that the business model of the pharmaceutical industry is undergoing fundamental changes" because of "tougher rebate negotiations with" PBMs. ¶ 168. On an earnings call that day, Schultz told investors that Novo's earnings were not at risk, because its financial results had "***nothing to do with competition***" and Novo's products would protect the Company from downward market trends. ¶ 92. Similarly, on August 6, 2015, after Sanofi reported lowered earnings "due to increased rebates" and predicted "further price erosion" (¶¶ 99-100), Defendant Sørensen reassured investors that Novo's earnings would be "flat to slight positive," because "we know the price picture," including "the numbers we know today for 2016" (¶ 101).

Defendants repeated such denials and false reassurances throughout the Class Period, with Sørensen stating that the Company would maintain market share "***based***

on the portfolio we have" (¶ 109), Brandgaard stating that he "***remain[ed] quite certain that we will see that growth***" (¶ 107), and Riis stating that Novo's drugs allowed Novo to "***withdraw ourselves from that dynamic***" (¶ 106) because, compared to competitors, "***we make our own decisions***" (¶ 108).

As early as the beginning of 2015, senior U.S. Novo executives internally warned the Individual Defendants that Novo's financial performance and forecasts were unsustainable because of the changing dynamics in the U.S. market. Despite those warnings, Defendants publicly denied any problems, and instead maintained unattainable guidance. Head of North America Operations Jesper Høiland has recounted multiple conversations and in-person meetings with senior Novo management including the Individual Defendants, during which Høiland informed them that Novo could not meet its long-term guidance due to U.S. pricing pressures, including from PBMs demanding increasing rebates. ¶¶ 22, 149. In response, senior management told Høiland that he had to meet corporate targets or they would "find someone else who would." ¶ 22. Høiland was abruptly fired when Novo was forced to revise its guidance downwards on October 28, 2016. *Id.*; ¶ 148.

E. Defendants Falsely Represented that Tresiba Would Insulate Novo from Pricing Pressures

To further justify Defendants' false claims that Novo was different, they touted Tresiba, a long-acting basal insulin drug that Novo planned to launch in 2016. Defendants told investors that Tresiba was a "next-generation product" that was

"superior" to – and allowed for premium pricing over – competitors' offerings. ¶¶ 106, 109-10. In response to an April 30, 2015 analyst question, for example, Sørensen flatly stated that Tresiba would "allow us to achieve 10% or more top-line growth in the diabetes market." ¶ 115. Novo later claimed that Tresiba would "further withdraw [Novo] from that [pricing] dynamic," and Riis called Tresiba "of course, a growth driver for us. That's why I think the [pricing] situations [between Novo and its competitors] are distinctly different." *Id*. Soon after Tresiba hit the U.S. market, Novo told investors that Tresiba was an "innovative product[]" that it could sell "at a high price . . . and there'll be a preference for such product." *Id*.

When analysts questioned why market pricing pressures did not impact Novo and its peers equally, Novo's answer was Tresiba. For example, during Novo's October 2015 earnings call and presentation, several analysts specifically asked how Novo's outlook remained positive despite reduced guidance and earnings from Sanofi and Eli Lilly. ¶¶ 105-07. Defendants Sørensen and Riis both claimed that Sanofi's guidance was down because of "what Tresiba delivered." *Id*. Contrary to their public representations, Defendants knew that Tresiba was not sufficiently differentiated from other drugs already on the market and could therefore not command premium pricing. Prior to the start of the Class Period, in April 2014, the French High Authority of Health rejected Novo's claim that Tresiba was an improvement over existing insulins. ¶ 113. Just months later, in August 2014, the

German Institute for Quality and Efficiency in Health Care, an independent, government-sponsored agency, separately concluded that Tresiba showed "no added benefit" over existing insulins that would justify premium pricing. ¶ 112.

By the start of the Class Period, the Company's senior officers internally acknowledged that Tresiba could not command premium pricing in the United States. ¶¶ 191-226. Beginning in 2015, senior U.S. executives specifically warned the Individual Defendants that Tresiba could not drive earnings in the United States, because Tresiba could not command premium pricing. ¶ 111. Høiland specifically warned that Novo could not drive profits through products like Tresiba because insulin is a mature product without an opportunity for meaningful improvement. ¶¶ 22, 149. Similarly, beginning in 2014, U.S.-based executives Sean Phillips (VP of Market Access Strategy) and Bill Breitenbach (VP of Marketing for the Basal Portfolio – which included Tresiba) informed the Individual Defendants in multiple conversations that Tresiba would not drive earnings in the United States due to the extreme pricing pressures and the fact that Novo could not substantiate premium pricing for the drug. ¶ 111. Breitenbach, in particular, told other U.S. executives that the Individual Defendants' projections were unrealistic, and was quoted as saying that Novo was "not going to get . . . plus 10% or 20% pricing for Tresiba." ¶ 155.

Other former Novo executives confirmed that the Individual Defendants knew

that Tresiba could not insulate Novo from pricing pressures. According to the VP of Diabetes Marketing, U.S. executives were "screaming that we were under pressure on price," which was met with a blunt response: "[t]oo freaking bad . . . . Deliver this number." ¶ 154. The VP of Diabetes Marketing further confirmed that Tresiba was nothing more than a "big puff of hot air," and not clinically differentiated from existing drugs. ¶ 155.

F. The Truth Comes to Light

After misleading investors throughout the Class Period, Defendants were forced to admit the truth in a series of corrective disclosures. On August 5, 2016, Novo issued its Q2 2016 results and disclosed that pricing pressures in the United States. contributed to poor results and lowered forecasts. In direct response, Novo's ADR price plummeted by nearly 16% over the next two trading days. ¶¶ 257, 259, 261. Deutsche Bank noted that the price drop "reflect[ed] the realization that Novo is not immune" to the pricing pressure of PBMs. ¶ 258. Similarly, Leerink observed that Novo faced "insulin pricing headwinds pressure." ¶ 260. Defendants continued to conceal the full impact of the PBM rebate scheme, and falsely insisted that Tresiba would enable premium pricing and long-term growth. ¶¶ 223-26, 262.

On September 1, 2016, Novo unexpectedly announced that Sørensen would "retire" at the end of the year, more than two years earlier than planned. ¶ 252. At the same time, Høiland abruptly left the Company. *Id*. Despite Novo's public

statement that his departure was "voluntary," Høiland later confirmed he was fired. ¶ 148. Analysts, including J.P. Morgan, reported that the departures "highlight[ed] that Novo felt they needed new management to lead the task of delivering US growth against the backdrop of US pricing pressure." ¶ 253. On September 29, 2016, Novo announced that it would reduce its workforce by approximately 1,000 employees, due to "a challenging competitive environment in 2017, especially in its large U.S. market." ¶ 263. In direct response, Novo's ADRs dropped over 4.5%.

On October 28, 2016, Novo slashed its annual long-term profit guidance from 10% to 5%, and warned that it expected 2016 sales growth to come in under previous guidance. ¶ 264. Novo admitted that the declines were because, "since February 2016, the competitive environment in the U.S. . . . has become more challenging, negatively impacting the price of . . . insulin." *Id.* Novo's ADR price plummeted by 13.8% in direct response. ¶ 266. Moreover, analysts began noting that Tresiba's "benefits are too small to drive market share gains." ¶ 140. Indeed, UnitedHealth's 2017 formulary excluded Tresiba because "it is not differentiated enough to warrant the price premium." ¶ 131.

By contrast, Novo's competitors confirmed that for years they had been aware of, and accounted for, market pricing pressures. On October 28, 2016 – the same day that Novo disappointed investors – an analyst asked Sanofi CEO Oliver Brandicort "why Novo is changing guidance into 2017 and beyond and Sanofi isn't."

¶ 137. Brandicort explained, "when [Sanofi] issued our guidance two years ago . . . we [took] into account a certain number of things that we felt were coming and that it's probably a tribute to . . . reasonable and cautious planning . . . ." *Id*.

Finally, on February 2, 2017, Novo further reduced its 2017 guidance, lowering sales growth to between -1% and 4% and operating profit to between -2% and 3%. ¶ 268. Novo disclosed that lower realized U.S. prices were negatively impacting sales, PBMs were taking larger rebates, and net pricing was declining. *Id*. Novo further admitted that it needed to "transform[] how we conduct business in the U.S.," directly sending its ADR price plummeting over 9%. ¶¶ 268, 270.

G. Novo Admits That Defendants Faced Pricing Pressures

One week after the Class Period, Defendants finally conceded the extent of the pricing pressures created by the PBMs demanding ever-increasing rebates. On February 9, 2017, Novo filed its 2016 Annual Report, which admitted, among other things, that PBMs "had strengthened their negotiating power, forcing pharmaceutical companies to either increase their rebates to get their products onto the PBMs' lists of approved, reimbursed products – or lose the contract." ¶ 159. Defendants further admitted, that, "[a]s a consequence . . . contract negotiations for 2017 resulted in higher-than-anticipated rebates to obtain broader coverage for our

products." ¶ 158.[3]

III. ARGUMENT

For purposes of a Rule 12(b)(6) motion to dismiss a § 10(b) action, "courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). To state a claim under § 10(b), a plaintiff must "allege defendants made a misstatement or an omission of material fact with scienter in connection with the purchase or the sale of a security upon which plaintiffs reasonably relied and plaintiffs' reliance was the proximate cause of their injury." *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 251 (3d Cir. 2009). Defendants challenge only Plaintiffs' falsity and scienter allegations. As discussed below, the Complaint adequately pleads both elements.

A. The Complaint Adequately Alleges Materially False and Misleading Statements and Omissions

To plead falsity under the PSLRA, a complaint need allege only facts "sufficient to support a reasonable belief as to the misleading nature of the statement or omission." *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 147 (3d Cir.

[3] Although Defendants claim that they had announced the higher-than-anticipated rebates in Novo's half-year financial statement (D. Br. at 11), what Defendants really told investors on August 5, 2016 was that "average prices after rebates are expected to be ***moderately lower***" (¶ 219), market access "is expected to remain largely unchanged" (*id.*), and ***investors should not "anticipate that we in any way revise our long-term targets***" (¶ 221).

2004) (citation omitted). A misstatement or omission of fact is material if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988).

1. Defendants Made Materially False and Misleading Statements and Omissions About Novo's Rebate Payments to PBMs

Throughout the Class Period, Defendants claimed that Novo's earnings were due to product-specific qualities, and that Novo set its pricing based on those qualities. ¶¶ 79-89. For example, in the Company's 2015 Annual Report, Defendants stated that "***[p]roduct success [in the United States] is largely based on competition on efficacy, safety, quality and price***" (¶ 83), and that "Novo Nordisk has been able to maintain the leading position in the overall diabetes care market through the ***quality and innovative value of the company's diabetes care products***" (¶ 208). Those statements were false and misleading.

In reality, because the PBMs control access to their formularies and thereby act as gatekeepers to the market, Novo was forced to offer ever-larger rebates to the PBMs in exchange for formulary access. ¶¶ 47-71. Novo's pricing and earnings thus relied on the size of rebates it was willing and able to pay PBMs, not the slight differences between Novo's insulin drugs and its competitors'. *E.g.*, ¶¶ 72-78. By November 2016, Defendants finally admitted as much, posting a statement on

Novo's website admitting that rebate payments were "***necessary in order for our medicines to stay on [payers'] preferred drug list or formulary***". ¶¶ 88. Only after the Class Period ended did Novo's new CEO, Lars Jørgensen, admit that Novo and PBMs had only recently started to discuss "contracts that determine what companies get paid depending on the medicines' efficacy," admitting that pricing and access were not previously determined by product-specific qualities. ¶ 89.

Courts routinely sustain allegations of false statements about the reasons underlying a company's financial results. *See, e.g.*, *Steiner v. MedQuist Inc.*, 2006 WL 2827740, at *16 (D.N.J. Sept. 29, 2006) ("attributing . . . revenues to legitimate business factors" was misleading where Defendants failed to disclose illicit "billing scheme"); *In re ATI Techs., Inc. Sec. Litig.*, 216 F. Supp. 2d 418, 436 (E.D. Pa. 2002) ("attributing [financial] performance to the wrong source[] is misleading under the securities laws"); *In re Providian Fin. Corp. Sec. Litig.*, 152 F. Supp. 2d 814, 823-24 (E.D. Pa. 2001) (sustaining claim of false statements attributing "income and revenue successes to Providian's 'customer-focused approach'").

Defendants willfully misconstrue the Complaint and present meritless arguments. First, Defendants suggest that Plaintiffs allege only that Novo "failed to disclose that it paid rebates in exchange for formulary placement." D. Br. 21. Plaintiffs' allegation is not that Defendants concealed and misrepresented Novo's rebate payments, but rather that Defendants falsely stated that Novo's financial

results were due to the attributes of its own drugs and making its "own decisions," instead of the truth – that "the PBMs completely controlled the markets," and formulary access was based upon the size of "rebates" paid, not products' "safety and efficacy." *See, e.g.*, ¶¶ 62, 210(d) & (f).

Second, Defendants contend that Plaintiffs allege Novo was required to accuse itself of an illegal kickback scheme.[4] D. Br. 20. Defendants miss the point. Even if investors knew that Novo paid rebates to PBMs, Defendants were not permitted to misrepresent the centrality of those rebates to Novo's market share and bottom line. Given Defendants' public statements about competition, rebate payments, and "product success," Defendants were obligated to speak fully and truthfully on those topics. *See Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1098 n.7 (1991) (although securities law "does not raise a duty of self-accusation, it enforces a ***duty to refrain from misleading***"); *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 2011 WL 3444199, at *9 (D.N.J. Aug. 8, 2011) ("once a defendant makes an affirmative statement or characterization about its business, it puts that subject 'in play' and assumes a duty, under the securities laws, to speak truthfully about that subject"); *Monk v. Johnson & Johnson*, 2011 WL 6339824, at

[4] Contrary to Defendants' mischaracterization, the Complaint alleges that lockstep pricing increases by Novo and its competitors placed the Company's earnings at substantial risk, because the increasingly large price increases necessary to pay ever-increasing rebates were unsustainable. *See* D. Br. 21 n.11; ¶¶ 66-71, 76.

*23 (D.N.J. Dec. 29, 2011) (same). Defendants were obligated to speak truthfully and not mislead investors, regardless of whether Novo's growing kickbacks to PBMs and/or lockstep price increases with its competitors were illegal.[5] Once Defendants touted the attributes of Novo's products as the primary reasons for its financial performance, that topic was "in play," and Defendants had a duty to speak fully and truthfully. They did not.

Third, Defendants mischaracterize Plaintiffs' allegations concerning the *quid pro quo* agreement to pay rebates to PBMs for formulary access. D. Br. 21-22. Even if investors were aware of rebate payments, Defendants misrepresented and concealed material information – including the amounts of rebates and the risk of a substantial hit to Novo's present and future earnings should Novo not pay sufficient rebates and, therefore, be excluded from a PBM's formulary. Investors thus lacked "transparency into the true nature and sustainability of [Novo's] drug sales and the

[5] Defendants' cases are in accord. *See Lewis v. Chrysler Corp.*, 949 F.2d 644, 652 (3d Cir. 1991) (securities law "limits only the duty to publicly admit to misconduct; . . . [not] a party's duty to disclose all material facts relating to the party's actions, including those that might relate to misconduct"); *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014) (legal duty satisfied by disclosure of "involvement in multiple legal proceedings and government investigations"); *In re Volkswagen "Clean Diesel" Mktg., Sales Practices, & Prods. Liability Litig.*, 2017 WL 2798525, at * (N.D. Cal. June 28, 2017) (sustaining claims where executives knew of consequences if concealed misconduct were discovered). Defendants cite *In re Citigroup, Inc., Sec. Litig.*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004), but the Southern District of New York has abandoned that standard in favor of the "better" standard in this Circuit, requiring defendant to disclose the "source of its success." *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 400-01 (S.D.N.Y. 2005).

risk of Novo meeting its financial forecasts," and "were not able to determine the likelihood that Novo would maintain its growth." ¶ 62.

The opacity of Novo's pay-to-play scheme with PBMs, specifically the amounts of growing rebate payments for formulary access paid for by unsustainable list-price increases, left investors in the dark about facts known to Defendants that risked harm to the Company's financial condition. In other words, Defendants' liability arises from misrepresented and concealed material facts – as all § 10(b) claims do – not merely the rebate payments. Novo itself admitted in late 2016 the need to "improve the system and create more transparency," and "transform[] the drug pricing system, which is incredibly complex and has resulted in a lot of confusion around what patients pay for medicines[.]" ¶ 63. Having only recently admitted the earlier lack of transparency into rebates, drug pricing, and formulary access, Novo cannot now credibly argue that it properly disclosed to investors all such material information during the Class Period.[6]

2. Defendants Made Materially False and Misleading Statements and Omissions About Novo's Exposure to Pricing Pressures

Defendants repeatedly misled investors into believing that Novo was

[6] Whatever may come of the government proposals to increase transparency (¶63), Defendants' position that the proposals would not bar rebates to PBMs at some point in the future is irrelevant to whether Novo misled its investors about the nature of the rebates and their impact on the Company during the Class Period.

protected from the intensifying pricing pressures that caused Sanofi and Eli Lilly to report lower earnings growth and downwardly revise their financial forecasts. ¶¶ 90-109. Those pressures prompted Sanofi to tell its shareholders during the Class Period that lower-than-expected growth was due to "***increased competitive pressure***" and "increased rebates" (¶ 90), and that sales volumes had increased (¶ 95) but profits declined "due to ***increased rebates granted to maintain favorable formulary positions with key payers***" (¶ 99). Eli Lilly also lowered guidance and disclosed its "***slowing insulin market outlook***." ¶¶ 105, 107.

Despite facing the same contemporaneous market pressures, however, Defendants repeatedly misrepresented to investors that its earnings were not at risk, because its financial results had "***nothing to do with competition***" and its products would protect Novo from downward market trends. ¶ 92. Investors credited those reassuring falsehoods. For example, on April 9, 2015, one analyst reported that although Sanofi warned of a worsening pricing environment, "***Novo, on the other hand, has said it is confident it will be able to raise prices in the US*** . . . ." ¶ 94. Similarly, on August 6, 2015, after Sanofi reported lowered earnings "due to increased rebates" and predicted "further price erosion" (¶¶ 99-100), Sørensen told investors that Novo had full visibility in the market and therefore a basis to report that its growth and earnings would be "flat to slight positive," because "we know the price picture," including "the numbers we know today for 2016" (¶ 101).

Moreover, in October and November 2015, numerous analysts directly asked why Novo's financial forecast did not reflect the pricing pressures that Sanofi and Eli Lilly had reported, and "***why you're different to competition***." ¶¶ 105-09. Defendants falsely reassured investors that Novo's results were secure. Sørensen, for example, stated that the Company would maintain market share "***based on the portfolio we have***" (¶ 109), while Brandgaard stated that he "***remain[ed] quite certain that we will see that growth***" (¶ 107), and Riis stated that Novo's drugs (including Tresiba) allowed Novo to "***withdraw ourselves from that dynamic***" (¶ 106) because, compared to competitors, "***we make our own decisions***" (¶ 108).

As the Third Circuit has held, a plaintiff states a claim under § 10(b) when it alleges that defendant executives are "specifically asked, directly and repeatedly, whether the company's pricing h[olds] steady despite the competitiveness of the market," and falsely represent the "pricing environment" as "stable." *Avaya*, 564 F.3d at 269-71; *see also Hutchins v. NBTY, Inc.*, 2012 WL 1078823, at *1, 6 (E.D.N.Y. Mar. 30, 2012) (sustaining § 10(b) claims where defendants knew that "pricing pressure would threaten or cause [the company] to suffer materially lower gross margins and operating results," an issue on which "the investment community w[as] keenly focused"); *City of Pontiac Gen. Emps.' Ret. Sys. v. Dell Inc.*, 2016 WL 6075540, at *1, 3 (W.D. Tex. Sep. 16, 2016) (sustaining alleged false statement "to expect in-line revenues" despite market pressures). Defendants' repeated, steadfast,

and direct assurances that Novo was insulated from the pricing pressures that plagued its competitors were false and give rise to liability.

Defendants wrongly contend that Novo's disclosures that pricing pressures existed should somehow exculpate them. D. Br. 24-25. That again mischaracterizes the Complaint. Plaintiffs allege that Defendants falsely touted Novo's financial outlook even in light of those disclosed hurdles. Defendants have ***admitted*** that their prior statements were false, lowering guidance and disclosing on February 2, 2017 that pricing pressures caused a "***transformation of how we conduct business in the US***." ¶ 146.[7] Moreover, to the extent that certain disclosures contradicted Defendants' false statements, investors' understanding of Defendants' conflicting disclosures are questions about materiality not properly resolved at the pleading stage. *See, e.g.*, *Va. Bankshares*, 501 U.S. at 1097 ("[N]ot every mixture with the true will neutralize the deceptive"); *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 280 n.11 (3d Cir. 1992) ("Materiality is a mixed question of law and fact, and the delicate assessments of the inferences a reasonable shareholder would draw from a given set of facts are peculiarly for the trier of fact."); *Tracinda Corp. v. DaimlerChrysler AG*, 197 F. Supp. 2d 42, 76 (D. Del. 2002) (rejecting materiality arguments "in the context of" Defendants' other disclosures).

[7] Defendants' reliance on *Chubb* is unavailing because, unlike here, the admissions in *Chubb* did not contradict the alleged falsehoods. *See Chubb*, 394 F.3d at 156.

Defendants relatedly argue that the Complaint does not allege that Novo and its competitors "were so similarly situated that external market forces would necessarily have affected them" equally. D. Br. 25. But that is precisely what the Complaint details. ¶¶ 64-78, 90-110. For years, Novo, Sanofi, and Eli Lilly raised prices in lockstep, and the commoditized nature of insulin meant that market factors would affect them "in the same way, at the same time" (D. Br. 25); *id.*; ¶¶ 79-89.

3. Defendants Made Materially False and Misleading Statements and Omissions About Tresiba

Defendants made numerous false and misleading statements about Tresiba, which they falsely told investors was a superior drug for which the Company could obtain premium pricing and gain market share. ¶¶ 111-18. For example, in direct response to analysts' questions, Defendants falsely stated that Tresiba "***will allow us to achieve 10% or more top-line growth in the diabetes market***"; was a "***premium product***" that warranted "***premium pricing***"; would allow Novo to "withdraw [it]sel[f]" from market pressures; was "***of course, a growth driver for [Novo]***"; and would "***take share in the market***" so that Novo "***will be pushing products up based on innovation*** . . . ." ¶ 115. Indeed, in May 2016, Novo falsely told investors that Tresiba was an "***innovative product[]***" that it could sell "***at a high price***," and Novo could "***uphold the value of all our portfolio based on that***." *Id*.

In truth, Tresiba was substantially similar to the insulin drugs already on the market for decades and could not support premium pricing, especially because

PBMs granted formulary access based on rebate size and would not allow premium pricing, even where incremental benefits actually existed. As early as 2014, German researchers had concluded that Tresiba showed "no added benefit" over existing insulins in the marketplace and, in the summer of 2015, German regulators rejected Novo's request to charge premium pricing for Tresiba. ¶ 112. France similarly rejected Novo's claim that Tresiba was an improvement over existing insulins. ¶ 113. Nonetheless, Defendants misrepresented Tresiba's purported premium characteristics and pricing. In Novo's 2Q 2015 Form 6-K, signed by Sørensen and filed a month after the Company pulled Tresiba from certain foreign markets, Novo explained in a "Management Statement" that there were "no changes" to Novo's "most significant risks and uncertainties" since the Company filed its 2014 Annual Report. ¶ 182. Then, after the FDA approved Tresiba on September 28, 2015, Sørensen again doubled down, telling investors that "we do believe [Tresiba] warrants a premium price . . . ." ¶ 186. Beginning in August 2016, Defendants were forced to admit that Tresiba failed to generate premium pricing. ¶¶ 117-18.

Defendants are liable for false statements about consumer demand for the Company's key products. *See, e.g.*, *In re Lucent Techs., Inc. Sec. Litig.*, 217 F. Supp. 2d 529, 558-59 (D.N.J. 2002) (sustaining claim of false statement that demand for product was "unprecedented" and supported positive guidance); *In re Vicuron Pharm., Inc. Sec. Litig.*, 2005 WL 2989674, at *1 (E.D. Pa. July 1, 2005) (sustaining

claim "that defendants made numerous materially false and misleading statements concerning [drug company's] lead product in development"); *In re Urban Outfitters, Inc. Sec. Litig.*, 103 F. Supp. 3d 635, 648 (E.D. Pa. 2015) (sustaining claim that CEO "misrepresented to investors . . . the demand for his company's products"). Defendants' repeated statements that Tresiba would enable Novo to avoid the negative effects of market pressures were false when made.

Defendants contend that, contrary to allegations of false statements that Tresiba would "insulate" Novo from pricing pressures, Novo "never said any such thing." D. Br. 25. Even if Defendants never used the word "insulate," that was precisely what they represented. For example, in direct response to analysts' questions about "the U.S. payer environment" and "price pressure," Defendants stated that because Tresiba was "***superior***," Novo "will ***be taking [market] share***," and Tresiba was an "***innovative product***" that Novo could sell "***at a high price***" and "***uphold the value of all our portfolio*** based on that." ¶ 216. And responding to an analyst's question in October 2015 about how Novo justified its positive outlook relative to Sanofi, Riis stated that "***Tresiba is, of course, a growth driver for us***" that allowed Novo to "***make our own decisions***" on pricing. ¶ 192. As Defendants knew at the time, including due to multiple foreign regulators' rejections of claims that Tresiba was a superior product that warranted premium pricing, those statements were false, and Tresiba would not protect Novo from the pricing pressures affecting

the rest of the U.S. insulin market or eliminate the true dynamics at play.

4. Defendants' SAB 104 Violations Evidence § 10(b) Liability

Under SEC Staff Accounting Bulletin 104 ("SAB 104"), companies must evaluate changes in revenue not "solely in terms of volume and price changes, but should also ***include an analysis of the reasons and factors contributing*** to the increase or decrease," which "should reveal underlying material causes of the matters described." ¶¶ 229-30. Defendants failed to disclose "known trends or uncertainties" with a material "impact on net sales or revenues or income," including that Novo's U.S. sales growth relied on paying increasingly larger and unsustainable rebates to PBMs. ¶¶ 231-42. Those omissions were misleading.

Defendants argue that SAB 104 does not itself impose a disclosure obligation under the federal securities laws. D. Br. 28-29. But whether SAB 104 violations themselves trigger § 10(b) liability, courts consider such violations as evidence of securities fraud – as Defendants' own cited cases recognize. *See Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 220-21 & n.24 (3d Cir. 2006) (holding that SEC interpretive release violations "create[] an issue of fact" concerning § 10(b) liability).[8] Because Defendants failed to disclose that revenues and market share

[8] *See also Doshi v. Gen. Cable Corp.*, 823 F.3d 1032, 1044 (6th Cir. 2016) (citing *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 163 (2d Cir. 2000) ("because SEC staff accounting bulletins 'constitute a body of experience and informed judgment' . . . we find [them] persuasive guidance for evaluating the materiality of an alleged misrepresentation")). Moreover, Defendants cite to *Oran v. Stafford*, 226 F.3d 275

were largely dependent on paying ever-growing, unsustainable rebates to PBMs, Defendants misled investors concerning the accuracy and sustainability of the Company's reported earnings and guidance.

5. Defendants' Misrepresentations Are Not Protected as Forward-Looking or by the PSLRA Safe Harbor

Contrary to Defendants' contention (D. Br. 36-40), their purported forward-looking statements were (1) not forward-looking, (2) knowingly false, and (3) not accompanied by meaningful cautionary language, and are therefore not protected by the PSLRA safe harbor. Under Third Circuit law, statements that a company was ***presently*** on track to achieve stated goals are actionable statements about the present. *See, e.g.*, *In re Enzymotec Sec. Litig.*, 2015 WL 8784065, at *10-11 (D.N.J. Dec. 15, 2015) ("statements relating to Enzymotec being 'well positioned for future growth,' or relating to [a key product] 'achieving rapid penetration' . . . related to then-existing conditions" (citations omitted)); *In re Aetna Inc. Sec. Litig.*, 34 F. Supp. 2d 935, 946 (E.D. Pa. 1999); *W. Palm Beach Police Pension Fund v. DFC Global Corp.*, 2015 WL 3755218, at *14 (E.D. Pa. June 16, 2015).

Defendants misrepresented present, known facts, not future circumstances.

(3d Cir. 2000), to argue that Item 303 does not give rise to disclosure obligations under federal securities law. Plaintiffs do not allege Item 303 violations. Further, "*Oran* actually suggested . . . that in certain instances a violation of Item 303 ***could*** give rise to a material 10b-5 omission, . . . so long as the omission is material . . . ." *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 103-04 (2d Cir. 2015).

For example, Defendants claimed Tresiba "***will allow us to achieve 10% or more top-line growth in the diabetes market***." ¶ 176; *see also, e.g.*, ¶¶ 186 ("***we do believe the product itself warrants a premium price***"), 191 (Tresiba "***is positive, so we can add that in***"), 194 ("***we are well positioned to . . . pursue the high end of the market, based on innovation***"). As discussed above at § II(E), however, at the time Defendants knew that, if approved, Tresiba was substantially similar to existing drugs that had been on the market for decades and accordingly did not warrant premium pricing or increases to Novo's market share, let alone 10% growth. Rather than protected projections, Defendants' statements about Tresiba misrepresented present, known facts about the drug.

Likewise, on August 6, 2015, Defendants told investors that in 2016, insulin prices would be "from flat to slight positive pricing" (¶ 183), expressly because of events that had already occurred: "we now have entered into contract for the remaining of 2015 and into 2016 . . . we know the price picture . . . with the numbers we know today for 2016, it would also indicate to us flat pricing for our insulin portfolio next year" (¶ 183). Again, Defendants' statement misrepresented present, known facts – at the time of the statement, "the price picture" indicated "2016 pricing and gross margins would decline significantly." ¶ 185(c). The next year, Defendants told investors that in 2017, "average prices after rebates are expected to be moderately lower" (¶ 219), market access "is expected to remain largely unchanged"

(*id.*), and investors should not "anticipate that we in any way revise our long-term targets." ¶ 221. Defendants told investors those statements were based on events that already occurred: "the majority of US formulary negotiations for 2017 have been finalized." ¶ 221. After the Class Period, Defendants admitted that, in fact, those "contract negotiations for 2017 resulted in higher-than-anticipated rebates to obtain broader coverage for our products." ¶ 158.

Even if forward-looking, however, Defendants' challenged statements are nevertheless actionable because they were knowingly false when made and their boilerplate warnings were not meaningful. *In re Bristol-Myers Squibb Sec. Litig.*, 2005 WL 2007004, at *52 (D.N.J. Aug. 17, 2005) (safe harbor does not protect "someone who warns his hiking companion to walk slowly because there might be a ditch ahead when he known with near certainty that the Grand Canyon is one foot away") (citation omitted). Defendants' vague warnings about "market risks" and "factors . . . [that] could cause actual results to differ" (D. Br. 39) did not describe risks that already had occurred or that would occur with "near certainty," including that Novo's growth was unsustainable because it was driven by ever-larger rebates to maintain formulary access, and that Defendants ***already knew*** Tresiba could not generate premium pricing. *E.g.*, ¶¶ 47-157, 272-75. Defendants' general warnings were not the type of "extensive [and] specific" language that the law requires, *Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000), especially where

Defendants' warnings were side-by-side with false representations that, for example, "[p]roduct success is largely based on competition on efficacy, safety, quality and price." D. Br. Ex. K at 36.[9]

6. The Complaint Does Not Allege Statements of Opinion

Defendants wrongly argue that their alleged misrepresentations and omissions are inactionable statements of opinion. D. Br. 36-38. "[M]agic words" such as "we believe" or "we think" at the start of a sentence containing "embedded statements of fact" do not turn a factual statement into an opinion or otherwise shield the statement. *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1327, 1331 (2015) ("those magic words can preface nearly any conclusion, and the resulting statements . . . remain perfectly capable of misleading investors").

As discussed above, the Complaint alleges misrepresentations about present, known facts. *Omnicare* does not protect Defendants, who misrepresented present facts and – to the extent any alleged misstatements were opinions – "lacked a reasonable basis for their expressed belief." *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 2015 WL 2250472, at *21 (D.N.J. May 13, 2015) (liability may

[9] Defendants' cited cases are inapposite. *See, e.g.*, *Avaya*, 564 F.3d at 271-74 (sustaining claims and dismissing only general statement about "overall financial picture rather than specific pricing levels"); *Bauer v. Eagle Pharm., Inc.*, 2017 WL 2213147, at *11 (D.N.J. May 19, 2017) (cautionary language, "in no uncertain terms," expressly warned that "FDA approval . . . [wa]s not guaranteed, [and] that the FDA may require additional, time consuming, testing").

lie where, "[e]ven if sincerely held, . . . a reasonable investor could understand Defendants' opinion statements to convey facts about their basis").

B. The Complaint Pleads a Strong, Compelling Inference of Scienter

Scienter is a "mental state embracing intent to deceive, manipulate, or defraud, and requires a knowing or reckless state of mind." *Avaya*, 564 F.3d at 252 (citations and quotation marks omitted). On a motion to dismiss, a court must consider "whether ***all*** of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 322-23 (emphasis in original). "In assessing the allegations holistically as required by *Tellabs*, the federal courts certainly need not close their eyes to circumstances that are probative of scienter viewed with a practical and common-sense perspective." *Avaya*, 564 F.3d at 272-73. The inference of scienter need be only ***as likely*** as any other inference. *Tellabs*, 551 U.S. at 324. Defendants make only piecemeal attacks on the numerous allegations evidencing scienter, and ***never*** offer any more plausible competing inference.

1. Defendants' Misrepresentations Concerned Novo's Core Operations, Which Evidences Scienter

Novo's insulin drugs, relationship with PBMs, and ability to withstand U.S. pricing pressures were keys to its ability to grow. *E.g.*, ¶¶ 92, 107, 243. Defendants' misstatements on those topics accordingly concerned Novo's core operations and products, which courts regularly hold evidences scienter. *See In re Cell Pathways*,

Inc., 2000 WL 805221, at *7 (E.D. Pa. June 20, 2000) (where fraud "relates to the core business of the company, knowledge of the fraud may be imputed to the individual defendants"); *Aetna*, 34 F. Supp. 2d at 953.

Given the Individual Defendants' direct involvement and visibility into the true pricing dynamics, the Individual Defendants knew or were severely reckless in not knowing that Novo's sales were driven not by product quality or efficacy, but by ever-growing rebates. For example, in response to an analyst's question on Novo's August 6, 2015 earnings call, Sørensen sought to justify Novo's 2016 guidance by explaining that "we now have entered into contract for the remain[der] of 2015 and into 2016," so "we know the price picture." ¶ 183. *Avaya* controls and is directly on point. There, as here, the defendant CFO falsely told investors that the company was not subject to the same pricing pressures negatively affecting the company's competitors, and denied that the company provided substantial discounts to its largest customers. 564 F.3d at 247-49. The Third Circuit held that a plaintiff pleads scienter

> when a defendant chief financial officer is specifically asked, directly and repeatedly, whether the company's pricing has held steady despite the competitiveness of the market. . . . Shareholders' central allegation is that Avaya engaged in massive discounting on an unusually large scale during the class period, [which the CFO] flatly denied in statements evincing certitude.

Id. at 269-70.

2. Defendants Knew that Tresiba Could Not Justify Premium Pricing

The core-operations doctrine also applies when defendants make misstatements regarding a company's core products, as Novo did with Tresiba. Novo's ability to command premium pricing for Tresiba in the face of pricing pressures was critical to the Company. To reassure investors, Defendants represented throughout the Class Period that Tresiba was a "next generation product," which "warrants a premium price" – and therefore was a "growth driver" that Novo "can promote" to "further withdraw ourselves from that [pricing] dynamic." ¶¶ 186, 191-92, 194. Defendants knew those statements were false when made. *See In re Viropharma Inc. Sec. Litig.*, 21 F. Supp. 3d 458, 473 (E.D. Pa. 2014) ("[T]he fact that sales of Vancocin comprised ViroPharma's 'core business,' also supports the inference that Defendants either knew or should have been aware of the issues concerning the drug's approval"); *Vicuron*, 2005 WL 2989674, at *6 ("[T]he importance of the [drug] to Vicuron supports at the very least a strong inference of recklessness on the part of the defendant officers").

Months before Defendants touted Tresiba's premium-pricing potential to investors, French and German regulators had already concluded that Tresiba was not a "superior" or "premium drug," and did not merit premium pricing. ¶¶ 112-13. In April 2014, French regulators concluded that Tresiba did not offer any improvement over existing insulins. ¶ 113. In August 2014, German regulators separately

concluded that Tresiba showed "no added benefit" over insulins that had been in the marketplace for decades. ¶ 112. But Defendants continued to hype Tresiba until the end of the Class Period as a "***next generation product***" that "***warrants a premium price***" and was therefore a "***growth driver***" that Novo "can promote" to "***further withdraw ourselves from that [pricing] dynamic***" impacting its competitors. ¶¶ 186, 191-226. Defendants do not address this powerful evidence of scienter at all. *See Viropharma*, 21 F. Supp. 3d at 473 (finding scienter where government agency informed defendants of drug inadequacy, which contradicted defendants' public statements). There can be no question that Defendants knew, or were reckless in disregarding, the impact of the findings by the German and French regulators.

3. Accounts of Former Novo Employees Support a Strong Inference of Scienter

The Complaint includes reports of former Novo employees, including the head of Novo's North America Operations Jesper Høiland, who was one of the Company's most senior officers. Those reports provide consistent, corroborating accounts that Defendants knew that the increasing rebates to PBMs were not sustainable, Novo's growth targets were not achievable, and Tresiba could not insulate Novo from pricing pressures. Courts in the Third Circuit credit such witness accounts where, as here, they have "sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Chubb*, 394 F.3d at 143 (quoting *Novak v. Kasaks*, 216 F.3d 300, 313-14

(2d Cir. 2000)).

The Complaint details multiple conversations between Høiland and senior Novo executives concerning the unsustainability of Novo's financial forecasts ***as early as 2015***. ¶ 149. Høiland made regular trips from the United States to Denmark to discuss U.S. business with Novo's senior management, including the Individual Defendants, during which Høiland specifically warned that Novo could not meet long-term growth targets due to U.S. pricing pressures. ¶¶ 149, 153. Those warnings were not mere "commonplace disagreements." D. Br. 32. In reality, Defendants relied on Høiland for reports on Novo's U.S. business and, rather than heed Høiland's warnings, senior management told him to meet corporate targets or they would "find someone else who would." ¶¶ 22, 149-50. Høiland's accounts of firsthand interactions with the Individual Defendants strongly support an inference of scienter. *See Viropharma*, 21 F. Supp. 3d at 473 (sustaining claim where witnesses were "at meetings with top [company] executives during which the [subject of the alleged fraud] was discussed").

Brian Lundstrom, a former Novo employee and large investor in the Company, described Høiland's conversations with Novo executives and further described Novo's internal forecasting meetings, which provides strong evidence of Defendants' scienter. ¶¶ 147-51. *See, e.g.*, *Berson v. Applied Signal Tech.*, 527 F.3d 982, 985 (9th Cir. 2008) (question is whether the witness "would be in a position to

infer" relevant facts, even if he did not "see" the facts "first-hand"). Defendants do not dispute that Lundstrom was in a position to know the facts attributed to him, and provide no authority for the suggestion that his conversations with Novo's Chairman, CEO (¶ 21), and Høiland should be discounted.

Firsthand reports from Novo's former Diabetes Marketing VP, who described Tresiba as a "big puff of hot air," further evidence scienter. ¶ 23. The Diabetes Marketing VP sat on Novo's Pre-Pricing Committee ("PPC"), which assessed market forces in the United States, analyzed the pricing environment, and issued reports to Novo executives in order to develop realistic expectations of future business. ¶¶ 23, 153. The PPC met quarterly to formulate recommendations and record them on business updates called "revised estimates" ("REs"), which were first presented to U.S. executives, including Høiland, and then to Danish executives, including the Individual Defendants. ¶ 153. The REs contained information on pricing, PBMs' rebates and rebate requests, and contractual negotiations with PBMs. ¶ 154. In addition, beginning in 2014, Sean Phillips (VP of Market Access Strategy) and Bill Breitenbach (head of marketing for Levemir) repeatedly warned the Individual Defendants that Tresiba would not drive earnings in the United States due to the extreme pricing pressures and the fact that Tresiba could not justify premium pricing. ¶ 111. Breitenbach, who spoke directly to Danish executives about the PPC's recommendations, told the Diabetes Marketing VP that Novo was "not going

to get Levemir plus 10% or 20% pricing for Tresiba." ¶ 155.

The former Novo employees' accounts are consistent and corroborative, which provides a cogent and compelling inference of scienter. *See, e.g.*, *Viropharma*, 21 F. Supp. 3d at 473 (scienter where former employees "were at meetings with top [company] executives" where topic of alleged false statements was discussed); *Local 731 I.B. of T. Excavators & Pavers Pension Trust Fund v. Swanson*, 2011 WL 2444675, at *12 (D. Del. June 14, 2011) (scienter where CWs' accounts corroborated each other); *In re Daou Sys., Inc.*, 411 F.3d 1006, 1015 (9th Cir. 2005) ("criteria for assessing reliability for confidential witnesses" include the "corroborative nature of the other facts alleged").[10]

4. Additional Facts Support Defendants' Scienter

Numerous other facts support scienter. *First*, Novo's compensation structure incentivized fraud, and evidences scienter. ¶¶ 247-51. Although Plaintiffs are not

[10] Defendants incorrectly read *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262 (D.N.J. 2007), and *In re Anadigics, Inc. Sec. Litig.*, 2011 WL 4594845 (D.N.J. Sep. 30, 2011). D. Br. 33. According to *Chubb*, which underlies both cases, the specificity Defendants raise is necessary only for ***confidential*** witnesses, and only when it is not "intuitively probable" that the witness possesses the information. *Chubb*, 394 F.3d at 149. The Complaint identifies Høiland, Lundstrom, Phillips, and Breitenbach by name. There can be no genuine dispute that, for Høiland, it is "intuitively probable" that the head of North America Operations would understand growth prospects and pricing pressure in the United States. Similarly, the Diabetes Marketing VP "analyzed the U.S. pricing environment and attempted to develop realistic expectations for future business," and "presented [] recommendations directly to U.S. executives." ¶¶ 147-51, 153. Those allegations are in stark contrast to the "vague references" and "personal opinions void of specific details" described in *Intelligroup*, 527 F. Supp. 2d at 278, and *Anadigics*, 2011 WL 4594845, at *32.

required to plead motive, "personal financial gain may weigh heavily in favor of a scienter inference." *Tellabs*, 551 U.S. at 325. Here, Sørensen, Brandgaard, and Riis had compensation packages specifically tied to annual goals that greatly incentivized the Individual Defendants to misrepresent the Company's financial condition. ¶¶ 247-51. During the height of the fraud in 2015, the Individual Defendants' cash and stock bonuses were as much as ***250%*** of their base salaries. *Id.* That "concrete and personal" financial gain weighs heavily in favor of finding Defendants' scienter. *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 633 (D.N.J. 2002); *see also, e.g.*, *Patriot Expl., LLC v. SandRidge Energy, Inc.*, 951 F. Supp. 2d 331, 351 (D. Conn. 2013) (scienter alleged where there was "a concrete and personal benefit to the [I]ndividual [D]efendants resulting from the fraud"); *In re Wellcare Mgmt. Grp. Sec. Litig.*, 964 F. Supp. 632, 639 (N.D.N.Y. 1997) (finding motive when defendant "actually realized a benefit, not merely had the potential for a benefit") (collecting cases).[11]

Second, the sudden departures of Sørensen and Høiland under suspicious circumstances support the inference of scienter. Sørensen and Høiland were two of Novo's senior executives directly involved in promoting Tresiba, and left Novo less than a month after it began to disclose the extent to which it was in fact exposed to

[11] *In re Party City Sec. Litig.*, cited by Defendants, is inapposite. *See* 147 F. Supp. 2d 282, 314 (D.N.J. 2001) (discounting allegation because plaintiffs failed to explain how the fraud increased defendants' compensation).

pricing pressures. ¶ 252. Sørensen's "retirement" came more than two years earlier than planned (*id*.) and, despite Novo's public characterization of Høiland's departure as "voluntary," Høiland later confirmed that he was fired (¶ 148). Analysts viewed those departures as hasty, unexpected, and directly related to the pricing pressures that Novo denied. In fact, J.P. Morgan reported that Høiland's departure "highlights that Novo felt they needed new management to lead the task of delivering US growth against the backdrop of US pricing pressure." ¶ 253. *Id*. The resignations of these individuals, including Novo's misrepresentation of Høiland's departure, "add to the overall pleading of circumstantial evidence of fraud." *Shenwick v. Twitter, Inc.*, 2017 WL 4642001, at *22 (N.D. Cal. Oct. 16, 2017) (suspicious "resignations or terminations constitute evidence of scienter"); *In re Scottish Re Grp. Sec. Litig.*, 524 F. Supp. 2d 370, 394 n.176 (S.D.N.Y. 2007).

Third, Defendants' false Sarbanes-Oxley certifications add to the inference of scienter. *See Rosky v. Farha*, 2009 WL 3853592, at *6 (M.D. Fla. Mar. 30, 2009) ("the person[s] signing the certification were severely reckless in certifying the accuracy of the financial statements"); *Hall v. The Children's Place Retail Stores, Inc.*, 580 F. Supp. 2d 212, 231-32 (S.D.N.Y. 2008).

IV. CONCLUSION

For the reasons set forth above and in the Complaint, Defendants' Motion should be denied.

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CARELLA, BYRNE, CECCHI, OLSTEIN,
BRODY & AGNELLO, P.C.
JAMES E. CECCHI

/s/ James E. Cecchi

5 Becker Farm Road
Roseland, NJ 07068
Telephone: 973/994-1700
973/994-1744 (fax)

SEEGER WEISS LLP
CHRISTOPHER A. SEEGER
DAVID R. BUCHANAN
550 Broad Street, Suite 920
Newark, NJ 07102
Telephone: 973/639-9100
973/639-9393 (fax)

SEEGER WEISS LLP
JENNIFER R. SCULLION
77 Water Street, 26th Floor
New York, NY 10005
Telephone: 212/584-0700
212/584-0799 (fax)

Co-Liaison Counsel and Executive Committee Members for the Class

ROBBINS GELLER RUDMAN
& DOWD LLP
SPENCER A. BURKHOLZ
LUKE O. BROOKS
RYAN A. LLORENS
ERIC I. NIEHAUS
ANGEL P. LAU
JEFFREY J. STEIN
655 West Broadway, Suite 1900
San Diego, CA 92101-8498
Telephone: 619/231-1058
619/231-7423 (fax)

ROBBINS GELLER RUDMAN
& DOWD LLP
SAMUEL H. RUDMAN
ROBERT M. ROTHMAN
58 South Service Road, Suite 200
Melville, NY 11747
Telephone: 631/367-7100
631/367-1173 (fax)

BERNSTEIN LITOWITZ BERGER &
GROSSMANN LLP
SALVATORE J. GRAZIANO
HANNAH G. ROSS
AVI JOSEFSON
KATHERINE M. SINDERSON
ADAM D. HOLLANDER
1251 Avenue of the Americas
New York, NY 10020
Telephone: 212/554-1400
212/554-1444 (fax)

Co-Lead Counsel for the Class

SAXENA WHITE P.A.
JOSEPH E. WHITE, III
BRANDON T. GRZANDZIEL
150 E. Palmetto Park Road, Suite 600
Boca Raton, FL 33432
Telephone: 561/394-3399
561/394-3382 (fax)

-and-

STEVEN B. SINGER
KYLA GRANT
4 West Red Oak Lane, Suite 312
White Plains, NY 10604
Telephone: 914/437-8551

888/631-3611 (fax)

Executive Committee Member