Michael R. Griffinger, Esq.
Brian J. McMahon, Esq.
Samuel I. Portnoy, Esq.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Tel.: (973) 596-4500
Fax: (973) 596-0545

-and-

James P. Rouhandeh, Esq.
Neal A. Potischman, Esq.
DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017

Attorneys for Defendants Novo Nordisk A/S, Lars Rebien Sørensen, Jesper Brandgaard, and Jakob Riis

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE NOVO NORDISK SECURITIES LITIGATION	No. 3:17-cv-209-BRM-LHG Document Filed Electronically CLASS ACTION

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

PRELIMINARY STATEMENT 1

ARGUMENT 3

I. Plaintiffs Fail to Plead a Material Misrepresentation or Omission 3

A. The Complaint Fails to Allege a Misrepresentation or Omission Regarding Rebates Paid to PBMs 3

B. The Complaint Fails to Allege a Misrepresentation or Omission Regarding U.S. Pricing Pressures 6

C. The Complaint Fails to Allege a Misrepresentation or Omission Regarding Tresiba®'s U.S. Launch 8

II. The SEC Bulletin and Releases Cited in the Complaint Do Not Create Any Disclosure Obligation and Cannot Give Rise to Liability 11

III. Plaintiffs Fail to Plead Particular Facts Giving Rise to a Strong Inference of Scienter 11

A. Statements from Witnesses and Confidential Informants 12

B. Plaintiffs' Additional Scienter Allegations Are Insufficient as a Matter of Law 15

C. Plaintiffs' Contentions Regarding the "Core Operations" Doctrine Do Not Give Rise to a Strong Inference of Scienter 15

IV. Novo Nordisk's Forward-Looking Statements and Statements of Opinion Are Immunized by the PSLRA and Are Inactionable 18

CONCLUSION 21

TABLE OF AUTHORITIES

CASES

PAGE(S)

In re Advanta Corp. Sec. Litig.,
180 F.3d 525 (3d Cir. 1999) 5

In re Aetna Inc. Sec. Litig.,
34 F. Supp. 2d 935 (E.D. Pa. 1999) 17, 19

In re Aetna Sec. Litig.,
617 F.3d 272 (3d Cir. 2010) 5

In re Amarin Corp. PLC Sec. Litig.,
2016 WL 1644623 (D.N.J. Apr. 26, 2016),
aff'd, 689 F. App'x 124 (3d Cir. 2017) 6

Berson v. Applied Signal Tech., Inc.,
527 F.3d 982 (9th Cir. 2008) 13

In re Biogen Inc. Sec. Litig.,
857 F.3d 34 (1st Cir. 2017) 17

In re Bristol-Myers Squibb Sec. Litig.,
2005 WL 2007004 (D.N.J. Aug. 17, 2005) 20

Cal. Pub. Emps. Ret. Sys. v. Chubb Corp.,
394 F.3d 126 (3d Cir. 2004) 14

In re Cell Pathways, Inc.,
2000 WL 805221 (E.D. Pa. June 20, 2000) 16

City of Edinburgh Council v. Pfizer, Inc.,
754 F.3d 159 (3d Cir. 2014) 6

Connelly v. Lane Constr. Corp.,
809 F.3d 780 (3d Cir. 2016) 7, 10

In re Donald J. Trump Casino Sec. Litig., 793 F. Supp. 543 (D.N.J. 1992),
aff'd sub nom., *In re Donald J. Trump Casino Sec. Litig.-Taj Mahal Litig.*,
7 F.3d 357 (3d Cir. 1993) 4, 8

In re Enzymotec Sec. Litig.,
2015 WL 8784065 (D.N.J. Dec. 15, 2015) 19

Gillis v. QRX Pharma Ltd.,
197 F. Supp. 3d 557 (S.D.N.Y. 2016) 3

Hall v. Children's Place Retail Stores, Inc.,
580 F. Supp. 2d 212 (S.D.N.Y. 2008) 15

Kelley v. Aerie Pharm., Inc.,
2016 WL 3437603 (D.N.J. June 20, 2016) 18

In re Ikon Office Sols., Inc. Sec. Litig., 131 F. Supp. 2d 680 (E.D. Pa. 2001),
aff'd sub nom., *In re Ikon Office Sols., Inc.*, 277 F.3d 658 (3d Cir. 2002) 10

Institutional Inv'rs Grp. v. Avaya, Inc.,
564 F.3d 242 (3d Cir. 2009) 16, 17

In re Intelligroup Sec. Litig.,
527 F. Supp. 2d 262 (D.N.J. 2007) 13, 14

In re Lucent Techs., Inc. Sec. Litig.,
217 F. Supp. 2d 529 (D.N.J. 2002) 10

Martin v. GNC Holdings, Inc.,
2017 WL 3974002 (W.D. Pa. Sept. 8, 2017) 16

Monk v. Johnson & Johnson,
2011 WL 6339824 (D.N.J. Dec. 19, 2011) 5

In re Merck & Co., Inc. Sec., Derivative, & "ERISA" Litig.,
2011 WL 3444199 (D.N.J. Aug. 8, 2011) 5

Nat'l Junior Baseball League v. PharmaNet Dev. Grp., Inc.,
720 F. Supp. 2d 517 (D.N.J. 2010) 16

In re Nice Sys., Ltd. Sec. Litig.,
135 F. Supp. 2d 551 (D.N.J. 2001) 10

Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund,
135 S. Ct. 1318 (2015) 21

Patriot Expl., LLC v. SandRidge Energy, Inc.,
951 F. Supp. 2d 331 (D. Conn. 2013) 15

Com. of Pa. ex rel. Zimmerman v. Pepsico, Inc.,
836 F.2d 173 (3d Cir. 1988) 13

Piccinetti v. Clayton, Myrick, McClanahan & Coulter, PLLC,
2017 WL 3879085 (D.N.J. Sept. 5, 2017) 21

Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.,
759 F.3d 1051 (9th Cir. 2014) 17

Rahman v. Kid Brands, Inc.,
736 F.3d 237 (3d Cir. 2013) 15, 16

Rosky v. Farha,
2009 WL 3853592 (M.D. Fla. Mar. 30, 2009) 15

Semerenko v. Cendant Corp.,
223 F.3d 165 (3d Cir. 2000) 20

Shapiro v. UJB Fin. Corp.,
964 F.2d 272 (3d Cir. 1992) 6

Shenwick v. Twitter, Inc.,
2017 WL 4642001 (N.D. Cal. Oct. 16, 2017) 15

In re Suprema Specs., Inc. Sec. Litig.,
438 F.3d 256 (3d Cir. 2006) 18

In re Urban Outfitters, Inc. Sec. Litig.,
103 F. Supp. 3d 635 (E.D. Pa. 2015) 10

In re Vicuron Pharm., Inc. Sec. Litig.,
2005 WL 2989674 (E.D. Pa. July 1, 2005) 10

In re ViroPharma Inc. Sec. Litig.,
21 F. Supp. 3d 458 (E.D. Pa. 2014) 13

W. Palm Beach Police Pension Fund v. DFC Glob. Corp.,
2015 WL 3755218 (E.D. Pa. June 16, 2015) 19

In re Wellcare Mgmt. Grp. Sec. Litig.,
964 F. Supp. 632 (N.D.N.Y. 1997) 15

Wilson v. Bernstock,
195 F. Supp. 2d 619 (D.N.J. 2002) 15

Yates v. Mun. Mortg. & Equity, LLC,
744 F.3d 874 (4th Cir. 2014) 17

Zucco Partners, LLC v. Digimarc Corp.,
552 F.3d 981 (9th Cir. 2009) 12

PRELIMINARY STATEMENT

The theory of plaintiffs' complaint—that Novo Nordisk misled the market about its financial prospects in 2015 and 2016—has numerous fatal defects. Chief among those flaws is that Novo Nordisk *met* its publicly disclosed financial guidance in 2015 and 2016, the two fiscal years at issue in this purported class action. Any claims based on Novo Nordisk's disclosures regarding *long-term* "aspirational" financial targets for the period extending beyond 2015 and 2016 likewise fail. Long-term targets are by definition both (1) forward-looking and (2) statements of opinion, rendering them inactionable under both the PSLRA and the Supreme Court's decision in *Omnicare*. These disclosures were accompanied by extensive cautionary language insulating these forward-looking opinions from suit.

Unable to plead falsity with respect to Novo Nordisk's financial guidance or long-term targets, plaintiffs attempt to base a claim on the allegation that Sanofi, a competitor, offered a more negative outlook for its business at an earlier point in time and that Novo Nordisk should have done so as well. As detailed in defendants' moving papers, Sanofi—but not Novo Nordisk—had a market-leading basal insulin product that faced impending competition from both (a) a generic competitor and (b) Novo Nordisk's next-generation basal insulin product, Tresiba®. Plaintiffs do not grapple with these facts. Plaintiffs ask this Court instead to set a dangerous precedent by seeking to require one company to answer

for another's more negative disclosures.

Plaintiffs' opposition also harps on the argument that Tresiba®—a product approved by the FDA and already selling well in various parts of the world—had seen market access setbacks in Germany and France. Plaintiffs nowhere contend with the fact, explained in defendants' motion, that Novo Nordisk *publicly and timely disclosed* the actions by German and French regulators. Plaintiffs have no coherent argument—let alone one with a well-pleaded factual basis—that Novo Nordisk misrepresented or failed to disclose any material fact, either about its own financial position and insulin products or how they compared to those of Sanofi.

Finally, plaintiffs' complaint does not adequately plead scienter. Plaintiffs' reliance on second-hand accounts from former employees cannot rescue their complaint. Plaintiffs nowhere include particularized, factual allegations indicating that senior executives responsible for financial reporting did not believe the company's disclosures. Moreover, even accepting as true that individuals in different business units disagreed about some aspect of budgeting or forecasting, that is not indicative of fraudulent intent. If an executive could be accused of securities fraud every time an underling argued to lower numbers that he had been asked to achieve, no public company could escape liability. The complaint lacks particularized, factual allegations showing that decision-makers at Novo Nordisk A/S in Denmark intended to deceive anyone about the company's prospects.

ARGUMENT

I. Plaintiffs Fail to Plead a Material Misrepresentation or Omission

A. The Complaint Fails to Allege a Misrepresentation or Omission Regarding Rebates Paid to PBMs

As defendants demonstrated in their motion, Novo Nordisk disclosed the extent of rebate payments to PBMs, their market power, and the potential impact of rebates on financial performance. (*See* MTD at 4-10, 21-25.) Unable to dispute the disclosures incorporated by reference into their complaint, plaintiffs simply assert in conclusory fashion that Novo Nordisk failed to share with investors material information about the "centrality" of rebates, and claim that Novo Nordisk only belatedly disclosed the "truth" that rebates were necessary for the company's drugs to remain on formulary.[1] (*See* Opp. at 16-18.) But, this is merely a different articulation of the same issue that Novo Nordisk disclosed and discussed with analysts during the class period.[2] (*See* MTD at 4-10, 21-25.) *See Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 588 n.17 (S.D.N.Y. 2016) ("no requirement to use any particular words").

In response, plaintiffs selectively quote various disclosures. First, plaintiffs

[1] These arguments are a "reboot" of plaintiffs' theory of the case. The complaint alleged *nine* times that the company concealed an alleged kickback scheme. (MTD at 5.) Plaintiffs have now abandoned this claim. (Opp. at 17-18.)

[2] Plaintiffs assert that PBMs' only criterion for formulary decisions was rebates. (Opp. at 3.) The complaint contains no factual allegations supporting a plausible inference that this is how PBMs operate or that Novo Nordisk knew it.

assert that Jakob Riis stated in October 2015 that the company could make its "own decisions" regarding pricing, which plaintiffs interpret as implying that the company had the power to dictate price to PBMs. (*See* Opp. at 18; *see also id.* at 2, 3, 9, 22, 26.) But, Mr. Riis was responding to a question about *Sanofi* and said instead that the company would not follow Sanofi's approach to pricing because Sanofi was facing new competition for its leading product. (*See* Ex. G at 13-14.)[3]

Second, plaintiffs cite two statements from Novo Nordisk's 2015 year-end filings: that "[p]roduct success . . . is largely based on competition on efficacy, safety, quality and price," and that Novo Nordisk was in "the leading position in the overall diabetes care market through the quality and innovative value" of its products. (Opp. at 16.) Plaintiffs have no argument that either of these general pronouncements was false or misleading, given the 2015 Annual Report's detailed disclosures regarding rebates and business risks. (*See* MTD at 6-9.) *See In re Donald J. Trump Casino Sec. Litig.*, 793 F. Supp. 543, 556 (D.N.J. 1992), *aff'd sub nom. In re Donald J. Trump Casino Sec. Litig.-Taj Mahal Litig.*, 7 F.3d 357 (3d Cir. 1993). In any event, generic statements that Novo Nordisk was "successful" or a "leading" company constitute, even at their outer limits, nothing more than

[3] The first sentence of plaintiffs' brief claims that Novo Nordisk told investors that it would "succeed over its competitors . . . because Novo had 'a very strong position with a gold standard product.'" (Opp. at 1.) That statement had nothing to do with insulin. It was part of Mr. Sørensen's explanation of why "one should expect that we will hold firm in the pricing of Victoza." (*See* Ex. C at 11.)

inactionable puffery. *See In re Aetna Sec. Litig.*, 617 F. 3d 272, 283 (3d Cir. 2010); *see also In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999).[4]

The motion to dismiss also demonstrated that Novo Nordisk's extensive disclosures about rebates and the PBMs' role in the market unambiguously conveyed to investors the importance of this market dynamic to Novo Nordisk's U.S. sales, overall results, and outlook. (*See* MTD 5-11, 21-22, 24-25; *see also* Compl. ¶¶ 101, 173, 176, 180, 183, 188, 192, 197, 203, 211.) Additionally, Novo Nordisk annually disclosed the amount paid in rebates. (*See* Compl. ¶ 240; *cf.* Ex. K at 64; MTD at 9.) And, the motion to dismiss demonstrated that Novo Nordisk disclosed the financial risks associated with increasing rebates. (*See* MTD at 5-11, 21-22, 24-25.)

In their opposition, plaintiffs ignore the company's disclosures, arguing that Novo Nordisk did not warn investors that ceasing to pay rebates in order to secure formulary access would pose a financial risk.[5] This claim strains credulity—it is

[4] Plaintiffs' cases (*see* Opp. at 17) do not suggest that courts have deemed general references to quality and innovative value to be false statements—only that it is misleading to falsely attribute financial success to specific products or initiatives.

[5] Plaintiffs note that a company must "speak fully and truthfully" about topics discussed in its disclosures. The cases plaintiffs rely upon only reinforce that they have failed to allege (much less with particularity) what defendants supposedly concealed. *Cf. In re Merck & Co., Inc. Sec., Derivative, & "ERISA" Litig.*, No. 05-1151, 2011 WL 3444199, at *9 (D.N.J. Aug. 8, 2011) (failing "to disclose . . . a link between Vioxx and increased CV [cardiovascular] events" when discussing drug's safety profile); *Monk v. Johnson & Johnson*, No. 10-4841, 2011 WL

axiomatic that losing the ability to sell products entails significant financial risk. Much of plaintiffs' argument turns on Novo Nordisk's expressed intention in late 2016 to improve the drug pricing system. Plaintiffs call this an "admission." (Opp. at 20.) But, Novo Nordisk's stated desire to work toward a better drug pricing system in no way implies that it misled investors about the existing system.

B. The Complaint Fails to Allege a Misrepresentation or Omission Regarding U.S. Pricing Pressures

Defendants' motion to dismiss demonstrated that the company extensively disclosed how U.S. pricing pressures were affecting the company,[6] and that it was not identically situated to Sanofi. (MTD at 5-11, 21-25.) In their opposition, plaintiffs argue that the defendants were overly optimistic,[7] misrepresented that

---

6339824, at *23 (D.N.J. Dec. 29, 2011) (failing to disclose "quality control deficiencies" and product recalls when discussing "issues of cost-cutting and quality assurance").

[6] The opposition does not address these disclosures. Instead, plaintiffs argue that any conflict between alleged "false statements" and the company's disclosures raises materiality questions to be decided later. (Opp. at 23.) Plaintiffs are wrong on the law. Courts must evaluate documents relied upon in the complaint to determine whether a facially plausible claim was alleged. *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 163 n.3, 166 (3d Cir. 2014). Plaintiffs' cases are not to the contrary. *See In re Amarin Corp. PLC Sec. Litig.*, 2016 WL 1644623, at *8 (D.N.J. Apr. 26, 2016), *aff'd*, 689 F. App'x 124 (3d Cir. 2017) (courts "must examine allegedly misleading statements in context"); *see also Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 280 n.11 (3d Cir. 1992) (pre-PSLRA case merely stating that materiality "is a mixed question of law and fact").

[7] Plaintiffs' allegations focus solely on factors affecting the U.S. market. Plaintiffs say nothing about the company's anticipated worldwide results, which are the basis for all of the financial guidance and targets at issue.

earnings were immune from risk, and should have mimicked Sanofi's disclosures. (Opp. at 20-21.) These arguments are fatally deficient.

First, plaintiffs do not dispute that defendants warned investors that increasing list prices to offset rebates was becoming untenable. (MTD at 8-9.)[8] Second, plaintiffs simply ignore the significant differences between Sanofi and Novo Nordisk. Plaintiffs reiterate that the complaint *says* that the companies were so similarly situated that external market forces would necessarily have affected them equally. (Opp. at 24.) But, they are different companies and the Court should not credit plaintiffs' mere conclusion. *See Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 786 n.2 (3d Cir. 2016).[9] This is particularly true because during the critical 2015 and 2016 periods—when plaintiffs claim Novo Nordisk should have been more bearish—Novo Nordisk *met* its financial guidance. (*See* MTD at 10-12.)[10] Having met its guidance, Novo Nordisk plainly was not overly optimistic.

---

[8] The complaint quotes a November 2015 presentation in which the company told investors that there would be "significant[ly] less" "opportunity going forward" for price increases of the type that had been taken in the past. (Compl. ¶ 194; *see also* Ex. H at 23 (referring to changing pricing dynamic and limited "pricing opportunity").

[9] The opposition also suggests that Eli Lilly's decision to lower its guidance is somehow relevant to assessing Novo Nordisk's conduct. (Opp. at 3, 10, 21.) The same analysis pertains. The complaint alleges no particularized facts showing that the two companies were identically situated.

[10] The opposition excerpts numerous statements to give the impression that the company conveyed limitless optimism. (*Compare, e.g.*, Opp. at 21 (Novo Nordisk's "financial results had 'nothing to do with competition'"), *with* Ex. B at

Moreover, defendants' motion explained that in 2015-2016, Sanofi was facing for the first time imminent generic competition for its blockbuster product, Lantus, (*id.* at 12-13), and that there were other material differences between the companies, including their product mixes (*id*. at 25). The opposition has no response.

C. The Complaint Fails to Allege a Misrepresentation or Omission Regarding Tresiba®'s U.S. Launch

Defendants' opening brief demonstrated that Novo Nordisk never said Tresiba® was certain to succeed or to insulate the company's results from pricing pressures. (MTD at 14-17, 25-27.) Rather, Novo Nordisk disclosed its specific bases for optimism, cautioned that the hoped-for impact likely would take time to achieve, and warned of the possibility that Tresiba®'s U.S. launch would not succeed—including because "reimbursement restrictions" posed a significant risk. (*Id.*) Relying on three allegations, the opposition argues that defendants knew that Tresiba® was "substantially similar and thus interchangeable" with other available insulins (Opp. at 4), and that PBMs would not allow premium pricing for it (*id.* at 24-25). None of plaintiffs' arguments are supported by particularized, factual

---

15 (what Novo Nordisk could "predict" about the coming year had "nothing to do with competition," because Novo Nordisk's predictions were based on contracts it had negotiated); Opp. at 22 (Mr. Riis said that Novo Nordisk could "withdraw ourselves from that dynamic [U.S. pricing pressure]"), *with* Ex. F at 11 (Novo Nordisk was "withdrawn" from the dynamic faced by Sanofi, which had to contend with new competition.). Recitation of misleadingly excerpted disclosures cannot state a claim. *See In re Donald J. Trump Casino Sec. Litig.*, 793 F. Supp. at 556.

allegations; and plaintiffs simply ignore the relevant disclosures.

First, plaintiffs' reliance on decisions by German and French regulators (*see id.* at 25, 34-35) is misplaced—these decisions are irrelevant as a matter of law because Novo Nordisk *disclosed* them. (*See* Ex. J at 4, 15, 18; Ex. K at 2.) The opposition does not acknowledge these disclosures, nor does the complaint suggest that Tresiba®'s track record in other countries was misrepresented. (*See* MTD at 25-26.) Plaintiffs' passing suggestion that the company should have modified the market risk warnings in its 2014 Annual Report (Opp. at 25) has no merit because that report *already warned* that the company might not launch Tresiba® in certain countries if it could not obtain market access on fair terms. (*See* Ex. A at 42.)

Second, plaintiffs' reliance on a confidential informant's own view of Tresiba® as a "big puff of hot air" (Opp. at 37) does not give rise to any inference of fraud. This informant's vague, subjective opinion of the drug does not call into question any of its distinguishing characteristics. (*See, e.g.*, MTD at 15-16, 26.)

Third, plaintiffs cite a second-hand report of a supposed statement by Mr. Høiland that insulin was "mature . . . without an opportunity for meaningful improvement" (Opp. at 11); but, again, one individual's opinion does not provide any factual basis for inferring that the drug was not clinically differentiated from predecessors. Nor does it call into question the ways in which Tresiba®, incontrovertibly, *is* different from older basal insulin products. (MTD at 15-16, 26;

Ex. E at 3, 9, 11 (longer duration of action, improved dosing flexibility, reduced number of required injections, and lower incidence of severe hypoglycemia).)

Plaintiffs' conclusory allegations that defendants knew Tresiba® was no different from other insulins must be disregarded. *See Connelly*, 809 F.3d at 786 n.2. Plaintiffs do not point to any factual allegations suggesting as much. "[C]onclusory allegation[s]" that statements about a product's anticipated performance are deceptive cannot serve as the basis for a securities fraud claim, because "misguided optimism . . . is not a cause of action."[11] *In re Nice Sys., Ltd. Sec. Litig.*, 135 F. Supp. 2d 551, 575 (D.N.J. 2001) (citation omitted); *see also In re Ikon Office Sols., Inc. Sec. Litig.*, 131 F. Supp. 2d 680, 702 (E.D. Pa. 2001), *aff'd sub nom. In re Ikon Office Sols., Inc.*, 277 F.3d 658 (3d Cir. 2002). Indeed, plaintiffs' complaint acknowledges that Tresiba® sold at a premium to other insulins. (*See* Compl. ¶ 124.) This fact alone defeats plaintiffs' claim that Tresiba® "could not support premium pricing." (Opp. at 24.)[12]

[11] Two of the cases plaintiffs rely upon concern allegedly false representations about *current* demand, not anticipated demand for a product not yet launched. *See In re Lucent Techs., Inc. Sec. Litig.*, 217 F. Supp. 2d 529, 538 (D.N.J. 2002); *In re Urban Outfitters, Inc. Sec. Litig.*, 103 F. Supp. 3d 635, 644, 646-47 (E.D. Pa. 2015). Plaintiffs' remaining case is irrelevant because, unlike here, the defendant did not disclose the results of a negative clinical study. *See In re Vicuron Pharm., Inc. Sec. Litig.*, 2005 WL 2989674, at *10 (E.D. Pa. July 1, 2005).

[12] Plaintiffs repeatedly cite Mr. Sørensen's April 2015 statement about achieving "10% or more top-line growth" as being about Tresiba®, (Opp. at 3, 10, 24, 29); but Mr. Sørensen said it was the company's "anticipation" that it would see such

II. The SEC Bulletin and Releases Cited in the Complaint Do Not Create Any Disclosure Obligation and Cannot Give Rise to Liability

In their opening brief, defendants demonstrated that neither SAB 104 nor the SEC Release could serve as an independent basis for liability. (MTD at 28-29.) Plaintiffs do not claim otherwise. Having abandoned any argument about the SEC Release, plaintiffs now argue that SAB 104 violations may be *evidence* of a 10b-5 violation. (*See* Opp. at 27.) But, the kind of analysis contemplated by SAB 104 is precisely what Novo Nordisk provided to investors. Throughout the class period, Novo Nordisk discussed increasing rebates and pricing pressures and the effects that those dynamics were having on Novo Nordisk's financial outlook. (*See, e.g.*, MTD at 5-11, 21-22, 24-25.)

III. Plaintiffs Fail to Plead Particular Facts Giving Rise to a Strong Inference of Scienter

Defendants demonstrated that plaintiffs failed to plead scienter because their complaint relies on (1) witness and confidential informant statements lacking the required specificity, and (2) boilerplate "additional scienter allegations" that courts routinely reject. (*See* MTD at 29-30.) The opposition claims that the statements are consistent and corroborative, that the additional scienter allegations contain

---

growth once it launched a *family* of drugs, including Tresiba®, (*see* Ex. C at 14). Plaintiffs also cite Mr. Sørensen's statement about "uphold[ing] the value of our portfolio" as being solely about Tresiba®, (Opp. at 3, 24, 26); the transcript shows it was not, (*see* Ex. M at 10 (premium paid for innovation in U.S. market would uphold the portfolio's value)).

supporting facts, and that the so-called "core operations" doctrine applies here. (Opp. at 32-40.) As set forth below, none of these arguments have merit.

A. Statements from Witnesses and Confidential Informants

As defendants explained in their opening brief, the vague statements from plaintiffs' witnesses and informants lack the specificity required to plead scienter. (MTD at 31-34.) Even accepting those allegations as true, they amount to nothing more than an allegation that Danish executives were more optimistic about the company's global financial outlook and Tresiba®'s prospects than were some U.S. personnel. *See, e.g.*, *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 999 (9th Cir. 2009) (disagreement among employees insufficient to create cogent or compelling scienter allegation). Plaintiffs also focus on the "consistency" of the statements allegedly made by different individuals. But, the opposition's marshalling of these statements, whether considered individually or in the aggregate, cannot demonstrate a strong inference of fraudulent intent.

As a threshold matter, the Court should disregard the allegations regarding what Mr. Høiland supposedly conveyed to Brian Lundstrom, a former Novo Nordisk employee who left the company many years before the alleged events and who sought to be a lead plaintiff here. (*See* MTD at 31.) Plaintiffs refer to "Høiland's accounts of firsthand interactions," leaving the impression that plaintiffs' attorneys spoke to him directly. (Opp. at 35-36.) They did not. (*See,*

e.g., Compl. ¶¶ 22, 110.) These statements are second-hand information that "present[ ] nothing more than the [individual's] beliefs based on . . . hearsay" and should be disregarded. *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 369 (D.N.J. 2007).[13]

Regardless, Lundstrom's account of what Mr. Høiland allegedly said lacks the required specificity to support an inference of scienter.[14] Nor do the statements suggest that any individual acted fraudulently. Plaintiffs allege that Danish executives told Mr. Høiland that he would be replaced if he could not meet his U.S. sales budget. (*See* Opp. at 9, 36.) This undermines plaintiffs' scienter claims. The most plausible inference is that the Danish executives *believed* that the U.S. budget was attainable. There is no allegation that the executives encouraged Mr. Høiland to engage in any misconduct to meet the numbers—or that he did so.

---

[13] Defendants noted in their opening brief that plaintiffs failed to allege "to whom Mr. Høiland spoke." (MTD at 32.) In response, plaintiffs claim (for the first time) that individual defendants were present during Mr. Høiland's alleged conversations with executives in Denmark. (Opp. at 36.) Under well-settled law, plaintiffs cannot amend their complaint via opposition briefing. *Com. of Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988).

[14] Plaintiffs cherry-pick a sentence from *In re ViroPharma Inc. Securities Litigation* to suggest that the court credited a witness statement based on the witness's mere presence at meetings. (Opp. at 36.) In fact, the court accepted the statements only after assessing the "detail provided by the confidential sources," their reliability, and other corroborating information. 21 F. Supp. 3d 458, 473 (E.D. Pa. 2014). Plaintiffs' other case, *Berson v. Applied Signal Tech. Inc.*, 527 F.3d 982, 985 (9th Cir. 2008), does not deal with confidential witness statements related to scienter.

Second, plaintiffs rely on statements from a former "Diabetes Marketing VP," including that Tresiba® was a "big puff of hot air." (Opp. at 37.) But such statements are insufficiently precise under Third Circuit standards.[15] (*See* MTD at 33.) In any event, the complaint does not allege that the Marketing VP shared this view with any executives during the class period, much less that they credited it.

Third, plaintiffs refer to statements from Phillips and Breitenbach, who apparently also never spoke to plaintiffs' counsel. Breitenbach's alleged statement that Novo Nordisk was "not going to get Levemir plus 10% or 20% pricing for Tresiba" (Opp. at 37-38) adds nothing to the scienter analysis because the complaint provides no basis for his view, or explanation of when he formed it or if he conveyed it to defendants. *Intelligroup*, 527 F. Supp. at 290. Plaintiffs' claim that Breitenbach and Phillips informed defendants "that Tresiba would not drive earnings," (Opp. at 11, 37), similarly fails to explain the factual basis for their opinions and why defendants were required to accept them, (*see* MTD at 33-34). Moreover, as noted *supra*, Tresiba® *did* sell at a premium, and plaintiffs do not and cannot dispute that Tresiba® sales increased over the relevant period.

[15] Plaintiffs only reply is to cite *California Public Employees' Retirement System v. Chubb Corp.* (Opp. at 35.) Plaintiffs fail to acknowledge, however, *Chubb*'s requirement that courts evaluate the "detail provided by the confidential sources." *Chubb*, 394 F.3d 126, 147 (3d Cir. 2004).

B. Plaintiffs' Additional Scienter Allegations Are Insufficient as a Matter of Law

Plaintiffs' additional scienter allegations are rote recitations that courts routinely reject. (*Id.* at 34-36.) First, plaintiffs' allegations regarding Novo Nordisk's compensation structure fail because they do not allege how the structure related to the alleged fraud.[16] Second, to accept an inference of scienter based on "sudden" personnel departures, courts require specific allegations (not found here) demonstrating relevance.[17] Third, courts have consistently held that the mere act of signing Sarbanes-Oxley certifications adds nothing to a scienter analysis.[18]

C. Plaintiffs' Contentions Regarding the "Core Operations" Doctrine Do Not Give Rise to a Strong Inference of Scienter

Plaintiffs also invoke the "core operations" doctrine. (Opp. at 32-35.) To

---

[16] Plaintiffs' cases are inapposite. *See Wilson v. Bernstock*, 195 F. Supp. 2d 619, 634 (D.N.J. 2002) (artificially inflating stock price to bolster compensation insufficient "generalized motive"); *Patriot Expl., LLC v. SandRidge Energy, Inc.*, 951 F. Supp. 2d 331, 350-52 (D. Conn. 2013) (scienter not based on incentive compensation); *In re Wellcare Mgmt. Grp., Inc. Sec. Litig.*, 964 F. Supp. 632, 639 (N.D.N.Y. 1997) (compensation probative because of particular bonus plan).

[17] *See, e.g.*, *Shenwick v. Twitter, Inc.*, 2017 WL 4642001, at *22 (N.D. Cal. Oct. 16, 2017) (resignation relevant where "[m]ultiple CWs" said the employee was "pushed out of the Company" because of the alleged fraud).

[18] *Cf. Rosky v. Farha*, 2009 WL 3853592, at *6 (M.D. Fla. Mar. 30, 2009) (finding that "glaring accounting irregularities or other 'red flags'" made SOX certifications probative of scienter); *Hall v. Children's Place Retail Stores, Inc.*, 580 F. Supp. 2d 212, 231-32 (S.D.N.Y. 2008) (requiring a showing of scienter separate from allegations that SOX certificates were materially false).

the extent that the doctrine exists post-*Tellabs*,[19] it is not a substitute for pleading scienter. Courts are required to examine the totality of the facts and circumstances in determining whether scienter has been alleged. *See Avaya*, 564 F.3d at 269; *see also Rahman*, 736 F.3d at 247. Through this lens, plaintiffs' efforts founder as a result of their failure to allege any facts with respect to the knowledge of any individual defendant.

Courts applying the doctrine have used it where there are compelling allegations of fraud by employees regarding a key aspect of a business in order to assess whether an executive who talks about verifiable, historical facts relating to that aspect of the business must have known that his own statements were false. A plaintiff must come forward with "particularized allegations showing that defendants had ample reason to know of the falsity of their statements." *Martin v. GNC Holdings, Inc.*, 2017 WL 3974002, at *14 (D.N.J. Sept. 8, 2017) (quotation marks omitted); *see also Nat'l Junior Baseball League v. PharmaNet Dev. Grp. Inc.*, 720 F. Supp. 2d 517, 557 (D.N.J. 2010). Without such allegations, there is no

[19] The Supreme Court has not addressed the question. In *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 246 (3d Cir. 2013), the Third Circuit found that the plaintiffs had failed to plead scienter. The court suggested in *dicta* that the panel that decided *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 268 (3d Cir. 2009), had applied the doctrine. While *Avaya* refers to the doctrine, there is no indication that the panel performed any "core operations" analysis separate from the analysis required under the PSLRA after *Tellabs*.

scienter.[20] *See, e.g.*, *Rahman,* 564 F.3d at 246-47 (citing *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1068 (9th Cir. 2008)).[21]

In *Avaya*, the court focused on allegations that the CFO was "specifically asked, directly and repeatedly, whether the company's pricing ha[d] held steady" and that he "flatly denied" that the company had engaged in discounting even though the company was alleged to have "engaged in massive discounting on an unusually large scale during the class period." 564 F.3d at 270. Here, by contrast, no defendant made any such denial as to *any* of the allegedly false or omitted statements. Plaintiffs simply cannot evade the PSLRA's scienter pleading requirement by tautologically claiming that, because the alleged fraud relates to an important part of Novo Nordisk's business, the defendants must have had knowledge of it. Imputation of knowledge as a basis for inferring scienter is

---

[20] Plaintiffs' pre-*Tellabs* cases are not to the contrary. *See In re Cell Pathways, Inc.*, 2000 WL 805221, at *2 (E.D. Pa. June 20, 2000) (particularized allegations that clinical study flaws were known); *In re Aetna Inc Sec. Litig.*, 34 F. Supp. 2d 935, 940-41 (E.D. Pa. 1999) (widespread integration problems were known).

[21] Other circuits that have adopted the doctrine have explained that satisfying it is "not easy" and requires "either specific admissions by one or more corporate executives of detailed involvement in the minutia of a company's operations" or "witness accounts demonstrating that executives had actual involvement in creating false reports." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1062 (9th Cir. 2014); *see also In re Biogen Inc. Sec. Litig.*, 857 F.3d 34, 41 (1st Cir. 2017) (confidential witness statements and core operations allegations insufficiently detailed to plead scienter); *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 890 (4th Cir. 2014) (core operations argument insufficient "without additional detailed allegations").

improper. *In re Suprema Specs., Inc. Sec. Litig.*, 438 F.3d 256, 282 (3d Cir. 2006).

IV. Novo Nordisk's Forward-Looking Statements and Statements of Opinion Are Immunized by the PSLRA and Are Inactionable

As set out in defendants' opening brief, Novo Nordisk's statements about its financial guidance and targets, pricing outlook, and expectations for Tresiba®'s performance were forward-looking, accompanied by cautionary language, and thus insulated from liability under the PSLRA. (*See* MTD at 36-40.) Plaintiffs claim that admittedly forward-looking statements on these three topics misrepresented "present facts" and, in the alternative, that Novo Nordisk's forward-looking statements were knowingly false when made and were not accompanied by meaningful cautionary language. (Opp. at 28-31.) Plaintiffs' arguments fail.

Plaintiffs cannot show that the statements about Tresiba®'s anticipated performance—made *prior* to its U.S. launch—misrepresented present facts. Statements about expectations for a drug that has not yet been brought to market are necessarily "forward-looking." *See Kelley v. Aerie Pharm., Inc.*, 2016 WL 3437603, at *3 (D.N.J. June 20, 2016). Moreover, plaintiffs' brief itself demonstrates that they have not alleged the misrepresentation of a present fact regarding market access and the pricing outlook. Plaintiffs contend that Novo Nordisk's guidance for 2016 (they do not address 2015) was false because "'the price picture' indicated '2016 pricing and gross margins would decline significantly.'" (*Id.* (citing Compl. ¶ 185(c).) But, plaintiffs' only support for this

alleged "fact" is a citation to *their own conclusory allegation*. Plaintiffs' *ipse dixit* assertion that the company's pricing guidance was false is not a "present fact."

Plaintiffs' argument that a post-class period disclosure about the impact of rebate negotiations on pricing suggests that an August 2016 statement misrepresented a present fact is similarly meritless. (*See* Opp. at 29-30.) The post-class period disclosure simply reiterates the same substantive information conveyed in August 2016. (*See* Ex. P at 1, 13 ("average prices after rebates are expected to be moderately lower" and "contract negotiations for 2017 have reflected an intensifying price competition").) And, the company's statements regarding anticipated sales growth identified in the complaint, (*see, e.g.*, ¶¶ 173 177, 180, 188, 197, 212, 219, 224), are quintessential forward-looking statements entitled to the protections afforded by the PSLRA.[22]

Plaintiffs next argue that, regardless of whether the statements are forward-looking opinions, they fall outside the safe harbor because they were "knowingly false when made" and accompanied by mere "boilerplate warnings." (Opp. at 30.)

[22] The cases cited by plaintiffs all involved misstatements regarding present facts. *See In re Enzymotec Sec. Litig.*, 2015 WL 8784065, at *11 (D.N.J. Dec. 15, 2015) (no safe harbor where defendants knew of "then-existing developments" and an ongoing investigation); *In re Aetna Inc. Sec. Litig.*, 34 F. Supp. 2d 935, 946 (E.D. Pa. 1999) (defendant concealed operational problems resulting from a completed merger); *W. Palm Beach Police Pension Fund v. DFC Glob. Corp.*, 2015 WL 3755218, at *14, *19 (E.D. Pa. June 16, 2015) (no safe harbor for deliberate lies about purportedly conservative lending practices).

In the single paragraph that the 40-page opposition devotes to this point, plaintiffs assert that Novo Nordisk "already knew" that "[its] growth was unsustainable" and that "Tresiba could not generate premium pricing." (*Id.*) But—yet again—plaintiffs offer no factual support for these conclusory assertions. Merely stating that a defendant "knew" or "must have known" its statements were false falls far short of the standard for pleading knowing falsity. (*See* MTD at 38.)

Plaintiffs' cautionary language argument is also fatally flawed. Plaintiffs do not even attempt to address the numerous examples of detailed cautionary language identified in defendants' opening brief. (*See id.* at 38-40.) Instead, the opposition declares that Novo Nordisk's warnings were "vague" and "did not describe risks that had already occurred or would occur with 'near certainty.'" (Opp. at 30.) But, defendants repeatedly cautioned investors about rebates, product pricing, and the outlook for Tresiba®, which lie at the heart of plaintiffs' complaint. (*See, e.g.*, MTD at 15, 40.) Novo Nordisk's forward-looking statements were thus accompanied by "the type of 'extensive [and] specific' language that the law requires," (*see* Opp. at 30 (quoting *Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000)), and are shielded from liability under the PSLRA.[23]

[23] The case cited by plaintiffs actually *confirms* that Novo Nordisk's cautionary language was meaningful. *See In re Bristol-Myers Squibb Sec. Litig.*, 2005 WL 2007004, at *54 (D.N.J. Aug. 17, 2005) (safe harbor satisfied by general warnings about FDA approval and market opportunity).

Finally, Novo Nordisk's statements of anticipation and belief are likewise protected as statements of opinion under *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318 (2015). (*See* MTD at 36-37.) Plaintiffs offer no factual support for the assertion that defendants "lacked a reasonable basis" for their expressed opinions about the company's financial outlook and Tresiba®'s prospects in the U.S. (*See* Opp. at 31-32; *see also* MTD at 26-27; Section I.C *supra*.)[24]

CONCLUSION

For the reasons set forth above and in defendants' motion to dismiss, defendants respectfully request that the complaint be dismissed with prejudice for failure to state a claim upon which relief can be granted.

Dated: December 18, 2017
Trenton, New Jersey

By: s/ Michael R. Griffinger

Michael R. Griffinger, Esq.
Brian J. McMahon, Esq.
Samuel I. Portnoy, Esq.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310

James P. Rouhandeh, Esq.
Neal A. Potischman, Esq.
DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017

Attorneys for Defendants Novo Nordisk A/S, Lars Rebien Sørensen, Jesper Brandgaard, and Jakob Riis

[24] The statements about Tresiba®'s prospects are also immaterial as a matter of law under the "bespeaks caution" doctrine. (*See* MTD at 40 n.23.) Plaintiffs nowhere refer to, and thus concede, the argument. *See, e.g.*, *Piccinetti v. Clayton, Myrick, McClanahan & Coulter, PLLC*, 2017 WL 3879085, at *2 (D.N.J. Sept. 5, 2017).

CERTIFICATE OF SERVICE

I, Michael R. Griffinger, an attorney duly admitted to practice in this District, hereby certify that, on December 18, 2017, I caused a true copy of Defendants' Reply Memorandum of Law in Further Support of Defendants' Motion to Dismiss Plaintiffs' Consolidated Amended Class Action Complaint and this Certificate of Service in accordance with the New Jersey District's Rules on Electronic Service.

Dated: December 18, 2017

GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4500

By: *s/* Michael R. Griffinger
Michael R. Griffinger

Attorneys for Defendants Novo Nordisk A/S, Lars Rebien Sørensen, Jesper Brandgaard, and Jakob Riis