UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE PHILIP MORRIS INTERNATIONAL INC. SECURITIES LITIGATION

No. 18-CV-08049 (RA)

OPINION & ORDER

RONNIE ABRAMS, United States District Judge:

Lead Plaintiffs Union Asset Management Holding AG and Teamsters Local 710 Pension Fund bring this class action against Defendants Philip Morris International Inc. ("Philip Morris" or the "Company"), André Calantzopoulos, Martin G. King, Patrick Picavet, Jacek Olczak, Manuel C. Peitsch, and Frank Lüdicke (collectively, the "Individual Defendants") alleging that, from July 26, 2016 through April 18, 2018, they committed securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10(b)-5. Plaintiffs allege that Defendants made false and misleading statements to the U.S. Food and Drug Administration ("FDA") about clinical trials Philip Morris conducted in connection with its Modified Risk Tobacco Product Application for a smoke-free electronic device entitled iQOS, as well as about the performance of iQOS in Japan.

Before the Court is Defendants' motion to dismiss Plaintiffs' Consolidated Amended Class Action Complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act. For the reasons that follow, Defendants' motion is granted.

BACKGROUND

I. Factual Background

Except where otherwise noted, the following facts are drawn from Plaintiffs' Consolidated

Amended Class Action Complaint (the "CAC"), Dkt. 92, and are assumed to be true for purposes of this motion. *See Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017).

A. The Parties

Lead Plaintiffs Union Asset Management Holding AG and Teamsters Local 710 Pension Fund represent all persons and entities, other than Defendants, who purchased or otherwise acquired the publicly traded securities of Philip Morris from July 26, 2016 through April 18, 2018 (the alleged "Class Period").

Defendant Philip Morris is a Virginia company that manufactures and sells cigarettes, other tobacco products, and other nicotine-containing products. CAC ¶ 22. Defendant André Calantzopoulos has served as Philip Morris's Chief Executive Officer since May 8, 2013 and previously served as the Company's Chief Operating Officer. *Id.* ¶ 23. Defendant Martin G. King has served as Philip Morris's Chief Financial Officer since January 1, 2018 and previously served as President of the Company's Asia Region. *Id.* ¶ 24. Defendant Patrick Picavet has served as Philip Morris's Director of Medical Affairs since February 2017 and was responsible for the planning and execution of the Company's scientific studies on its smoke-free products. *Id.* ¶ 25. Picavet previously served as the Company's Director of Clinical Assessment from August 2014 through January 2017. *Id.* Defendant Jacek Olczak has served as Philip Morris's Chief Operating Officer since January 1, 2018 and previously served as the Company's Chief Financial Officer during the Class Period until his appointment as Chief Operating Officer. *Id.* ¶ 26. Defendant Manuel C. Peitsch served as Philip Morris's Chief Scientific Officer for Reduced-Risk Products during the Class Period. *Id.* ¶ 27. Defendant Frank Lüdicke was Philip Morris's Chief Medical Officer during the Class Period and oversaw clinical trials for the Company's smoke-free products. *Id.* ¶ 28.

B. Development of IQOS as an Alternative to Traditional Cigarettes

As Philip Morris's sales of traditional cigarettes have declined in recent years, the Company has invested over $4 billion in the development of smoke-free alternatives. *Id.* ¶¶ 3, 32. These products, known as reduced-risk products ("RRPs") are marketed as presenting a lower health risk than traditional cigarettes. *Id.* ¶ 3. In September 2017, Philip Morris announced it had pledged up to $1 billion to launch a foundation dedicated to eliminating smoking worldwide. *Id.* ¶ 33. Upon making this announcement, Defendant Calantzopoulos told the *Financial Times* that "[o]ur efforts are squarely focused on ultimately replacing cigarettes with smoke-free products, by offering the millions of men and women who continue to smoke a better alternative. We are standing at the cusp of a true revolution." *Id.* Philip Morris's website similarly states, "We're building PMI's future on smoke-free products that are a much better choice than cigarette smoking." *Id.* ¶ 34.

Philip Morris's flagship RRP, "iQOS," is an electronic device that heats specially designed tobacco units to release a flavorful nicotine-containing vapor without combustion, fire, ash or smoke. *Id.* ¶ 35. iQOS contains three main components: a heated tobacco unit (called HEETS or HeatSticks), an iQOS holder and a charger. *Id.* iQOS was first introduced in the city of Nagoya, Japan in late 2014 and launched nationwide in Japan in the spring of 2016. *Id.* ¶ 38. During the Class Period, Japan was the only country in which iQOS was available nationwide. *Id.* Philip Morris promoted iQOS in Japan as a less harmful product than conventional cigarettes. *Id.* ¶ 39. This approach helped persuade Japanese officials to classify the iQOS device differently than traditional cigarettes, resulting in a lower tax rate and exempting it from ordinances banning smoking in public places. *Id.* ¶¶ 39-41.

C. Philip Morris's Modified Risk Tobacco Product Application and Claims Regarding its Clinical Studies

Philip Morris faced a more demanding regulatory landscape in the United States than in Japan. *Id.* ¶ 42; Mem. in Supp. of Defs.' Mot. to Dismiss ("Defs.' MTD"), Dkt. 109, at 3. Pursuant to the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), Pub. L. No. 111–31, 123 Stat. 1776 (2009), *codified at* 21 U.S.C. § 387 *et seq.*, Philip Morris was required to obtain FDA approval to sell iQOS in the United States and to market it as a Modified-Risk Tobacco Product ("MRTP")—a product that presents a lower risk of tobacco-related disease and less harm than traditional tobacco products. CAC ¶ 42. In December 2016, Philip Morris submitted its Modified-Risk Tobacco Product Application ("MRTPA") and requested orders to market iQOS as both a reduced-risk tobacco product and reduced-exposure tobacco product under Section 911(g)(1) and Section 911(g)(2) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), *codified at* 21 U.S.C. § 387k(g). CAC ¶¶ 45, 46. Section 911(g)(1) of the FD&C Act provides that the FDA may issue a modified risk market order for a tobacco product if the applicant satisfies a two-prong test. *See* 21 U.S.C. § 387k(g)(1). The applicant must demonstrate that the product "as it is actually used by consumers, will (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." *Id.*

Philip Morris made three claims in support of its application for an MRTP marketing order:

> Claim 1 under § 911(g)(1): "Switching completely from cigarettes to the iQOS system can reduce the risks of tobacco-related diseases."
>
> Claim 2 under § 911(g)(1): "Switching completely to iQOS presents less risk of harm than continuing to smoke cigarettes."
>
> Claim 3 under § 911(g)(2): "Switching completely from cigarettes to the iQOS system significantly reduces your body's exposure to harmful and potentially

harmful chemicals."

Id. ¶ 48.

Philip Morris outlined the steps it took to assess whether iQOS poses less risk of harm or disease than conventional cigarettes, including conducting eight "clinical studies with adult smokers according to the principles of Good Clinical Practice" in the U.S., Europe, and Japan between 2013 and 2015. *Id.* ¶¶ 50, 63. Good Clinical Practice ("GCP") is an "international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects." *Id.* ¶ 56. FDA guidelines provide that clinical studies should adhere to GCP. *Id.* ¶ 66. Philip Morris repeatedly emphasized its compliance with GCP. *See, e.g., id.* ¶¶ 50, 54, 167, 173, 175, 218, 236, 240, 249, 255. Philip Morris published its studies on ClinicalTrials.gov, a U.S. government database managed by the National Institute of Health, *id.* ¶ 53, and represented that its clinical studies supported its claims under both §§ 911(g)(1) and (g)(2) of the FD&C Act. *Id.* ¶ 51. For example, the Company stated that the results of its clinical trials on iQOS "provide evidence to substantiate both a reduced risk claim . . . and a reduced exposure claim," and the "totality-of-the evidence presented," including the results of its clinical studies, "demonstrates that smokers who completely switch from cigarette smoking to THS should have a significant reduction in harm and the risk of tobacco-related diseases." *Id.* ¶ 54.[1]

On February 14, 2017, Philip Morris filed its Form 2016 10-K, which stated, *inter alia*, that the results from the iQOS studies "are generally consistent with the expected direction of change and indicate that switching completely to IQOS led to an overall improvement of clinical risk markers affected by smoking after only three months." *Id.* ¶¶ 197-200, 317. The following day, Calantzopoulos sold 35,000 shares of his personally held Philip Morris stock for proceeds of

[1] THS stands for "Tobacco Heating System." CAC ¶ 46.

nearly $3.6 million. *Id.* ¶¶ 316-17.

In May 2017, the FDA formally accepted and filed the Company's MRTPA for substantive scientific review. *Id.* ¶ 45.

D. Reuters Article and Koval's Allegations Regarding Deficiencies in Clinical Studies

On December 20, 2017, *Reuters* released an investigative report detailing "irregularities" in the clinical studies underpinning the Company's FDA application for iQOS. *Id.* ¶ 7; McDonough Decl. Ex. 12 ("*Reuters* Article"). *Reuters* interviewed six of the eleven principal investigators responsible for five of the eight clinical trials as well as Tamara Koval, a former Philip Morris scientist who co-wrote the protocol for the clinical studies and coordinated between Philip Morris and those contracted to run the clinical studies. CAC ¶¶ 62, 65. Plaintiffs also interviewed Koval directly. *Id.* ¶ 62.

According to Koval, and as reported in *Reuters*, several of the researchers and principal investigators were not fluent in English and thus could not have properly understood the trainings on clinical trial protocols that were conducted in English without any translators present. *Id.* ¶ 67; *Reuters* Article at 5. One principal investigator at a Tokyo clinic, Masayuki Sugimoto, told *Reuters* that his clinic was "heavily in the red" and that he had little confidence that the participants in the experiment he ran were telling the truth about their smoking history. CAC ¶ 70; *Reuters* Article at 3. When *Reuters* asked Sugimoto about the urine tests his clinic administered to confirm whether participants were smokers, he stated, "I don't know whether they were done that rigorously." CAC ¶ 70; *Reuters* Article at 3. *Reuters* also reported on another study site where investigators collected samples before getting informed consent forms signed by participants and ultimately had to discard data from 56 participants. CAC ¶ 72; *Reuters* Article at 3-4. When *Reuters* reached the principal investigator at the site by phone, she said, "My specialty is urology and I don't know anything about tobacco, so I cannot talk." CAC ¶ 73; *Reuters* Article at 4.

Reuters also reported—and Koval purportedly confirmed to Plaintiffs—that the urine samples collected in one Polish study exceeded the limits of what a human being can produce in a single day. CAC ¶¶ 80-82; *Reuters* Article at 5-6. According to Koval, several subjects reported 12-18 liters of urine when the normal urine samples produced by humans are between 2-4 liters. CAC ¶ 80. Koval claimed that when she raised these concerns with Defendant Picavet, who was helping to lead the effort to obtain FDA approval for iQOS, he excluded her from meetings. *Id.* ¶ 81; *Reuters* Article at 1, 6. Plaintiffs allege that Philip Morris included the tainted samples in its analysis and marked them as "adverse events" rather than excluding them altogether. CAC ¶¶ 82, 258; *Reuters* Article at 6. *Reuters* reported, however, that it "did not find any evidence that the outcome of the experiments presented by the company to the FDA was manipulated or falsified." *Reuters* Article at 2.

The day the *Reuters* article was published, the Company's stock price fell $3.75 per share to close at $104.37 per share—a loss of $5.8 billion in market capitalization. CAC ¶ 8. The CAC also includes an allegation reported by Koval that was not included in the *Reuters* article—that another clinical study conducted in Japan contained over 100 contaminated urine samples that were collected and aggregated into a single jar. CAC ¶ 83. Koval alleges that these contaminated samples were included in Philip Morris's FDA application without any disclosure of the GCP violation. *Id.* ¶ 84.

E. Philip Morris Allegedly Concealed Adverse Studies

According to Plaintiffs, Philip Morris conducted at least four additional scientific studies that produced results that contradicted the Company's claim that iQOS is less harmful than cigarettes. *Id.* ¶¶ 85-89. Plaintiffs allege these studies showed that a significant number of toxic or potentially toxic compounds were found in the aerosol generated by the iQOS that were not found in conventional cigarettes. *Id.* ¶ 89. Additionally, the studies reflected that 17-18 of the

FDA's list of 93 harmful and potentially harmful constituents ("HPHCs") were equally elevated in iQOS as they were in conventional cigarettes. *Id.* ¶¶ 87-89. Plaintiffs allege these results were concealed from investors for a large part of the Class Period and were only submitted to the FDA in a belated December 8, 2017 amendment—one year *after* the Company submitted its initial application to the FDA in December 2016. *Id.* ¶ 85. However, two of the four studies had already concluded in June 2016—half a year *before* Philip Morris submitted its MTRPA. *Id.* In other words, Plaintiffs allege that Philip Morris waited a year and a half to disclose adverse results from the first two studies to the FDA and the public. *Id.* ¶ 86. The remaining two studies concluded in January 2017—nearly a year before Philip Morris filed its amendment to the FDA. *Id.* ¶ 85.

Plaintiffs contend that Philip Morris also sent a "threatening letter" to the bosses of researchers whose independent study examining the risk of iQOS found higher levels of several toxic compounds in iQOS than Philip Morris had claimed. *Id.* ¶¶ 90-93. Plaintiffs allege that such a letter is highly unusual in the scientific community. *Id.* ¶ 93.

F. FDA Advisory Committee Vote on Philip Morris's Modified Risk Tobacco Product Application

The FDA convened an advisory panel of industry experts—the Tobacco Products Scientific Advisory Committee ("TPSAC")—to review Philip Morris's MRTPA for iQOS. *Id.* ¶ 95. The FDA published a briefing document on December 22, 2017 that detailed its preliminary findings on Philip Morris's MRTPA and raised a number of concerns. *Id.* ¶¶ 96-98. With respect to the four studies that were submitted in the December 8, 2017 amendment, the FDA noted that "the application provided additional aerosol testing information indicating there were compounds of toxicological concern present in higher quantities in *HeatSticks* aerosols than in reference cigarette smoke." *Id.* ¶ 97.

On January 24 and 25, 2018, the TPSAC gathered to hear presentations from various Philip

Morris representatives and outside experts. *Id.* ¶ 99. At the conclusion of the two-day TPSAC Meeting, the Committee called a vote on several questions concerning the Company's submission. *Id.* ¶ 102. These questions, and the responses, included, *inter alia*, the following:

> 1. Discuss evidence related to the health risks of the IQOS system and the appropriateness of the proposed modified risk information.
>
> > a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases."? (Vote)
> >
> > **Yes – 0 No – 8 Abstain – 1**
>
> > b. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes."? (Vote)
> >
> > **Yes – 4 No – 5 Abstain – 0**
>
> 3. Discuss evidence regarding the likelihood that existing combusted cigarette smokers will initiate use of the IQOS system, completely switch to IQOS, and/or become long-term dual users of IQOS and combusted cigarettes.
>
> > a. What is the likelihood that that U.S. smokers would completely switch to use of the IQOS system? (High/Medium/Low)
> >
> > **High – 0 Medium – 2 Low – 7 Abstain – 0**
>
> 5. Discuss evidence regarding consumer comprehension and perceptions of the proposed modified risk labeling and advertising.
>
> > a. Has the applicant demonstrated that, after viewing the proposed modified risk labeling and advertising, consumers accurately understand the risks of IQOS use as conveyed in the modified risk information? (Vote)
> >
> > **Yes – 0 No – 9 Abstain – 0**

Id.; McDonough Decl. Ex. 15. Accordingly, a majority of the Advisory Committee voted, in relevant part, that: (i) Philip Morris failed to demonstrate that its scientific studies have shown

that switching completely from cigarettes to the iQOS system can reduce the risks of tobacco-related diseases; and (ii) Philip Morris failed to demonstrate that switching completely to iQOS presents less risk of harm than continuing to smoke cigarettes. CAC ¶ 103. The TPSAC's vote constitutes a non-binding recommendation to the FDA. *See* Defs.' MTD at 8; McDonough Decl. Ex. 14, at 18.

Defendants, however, point out that the Advisory Committee voted in favor of Philip Morris's reduced exposure claim. *See* Defs.' MTD at 8. Specifically, the Advisory Committee voted as follows:

> 2. Discuss evidence related to human exposure to harmful or potentially harmful chemicals when combusted cigarette smokers completely switch to the IQOS system, including the implications of changes in exposure for long-term disease risk and the appropriateness of the proposed modified risk information.
>
> > a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."? (Vote)
> >
> > **Yes – 8 No – 1 Abstain – 0**
> >
> > b. If the answer to question 2a is "yes", has the applicant demonstrated that the reductions in exposure are reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality? (Vote) [To be answered by Committee members who voted "yes" to 2a.]
> >
> > **Yes – 2 No – 5 Abstain – 1**

McDonough Decl. Ex. 15.

The day of the TPSAC vote, on January 25, 2018, the *New York Times* published an article entitled "F.D.A. Panel Rejects Philip Morris's Claim That Tobacco Stick Is Safer Than Cigarettes," reporting the Committee's recommendation for the rejection of Philip Morris's bid to market iQOS as safer than traditional cigarettes in the United States. CAC ¶ 104. The article

stated that in an eight-to-one vote, the "panel rejected the company's contention that 'scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases.'" *Id.* That same day, the Company's stock price fell from $110.06 per share to $107.49 per share—a loss of $4.8 billion in market capitalization. *Id.* ¶ 105.

G. Defendants' Positive Projections About Growth in Japan in 2018

On February 8, 2018, Philip Morris announced its financial results for the fourth quarter and year ended December 31, 2017, and reported that it had shipped 15.7 billion HeatSticks—a 60% increase from the prior quarter and a 325% year-over-year increase. *Id.* ¶¶ 120-21. The Company also announced that the market share for HeatSticks in Japan had increased during the fourth quarter, from 11.9% in the prior quarter to 13.9%. *Id.* ¶ 122. During an earnings call that day, Defendant Calantzopoulos stated that the Company's growth in Japan was the result of an "increasing demand for HeatSticks, which we expect to grow further in the first quarter [of 2018] following a planned lifting of the restriction on iQOS device sales." *Id.* ¶¶ 123, 278. He declared, "We thus begin 2018 in excellent shape, with the supply of HeatSticks no longer an issue. The shipments of HeatSticks now shifted from air to lower-cost sea freight, and the capacity limits on IQOS device is behind us as of this month." *Id.* ¶ 280. Finally, Calantzopoulos stated, "there's nothing in the horizon that would affect—that would cause any change in what happened in the previous years." *Id.* ¶¶ 124, 283.

On February 21, 2018, Defendants Calantzopoulos, King, and Olczak each spoke on behalf of Philip Morris at the Consumer Analyst Group of New York ("CAGNY") conference. *Id.* ¶¶ 127, 287. During their remarks, these Defendants represented that Philip Morris was experiencing continued growth. In particular, Defendant Calantzopoulos stated that Philip Morris was a "growth stock" and that "8% plus currency-neutral net revenue growth is not just a 2017 or 2018 phenomenon." *Id.* ¶¶ 128, 287. Defendant Olczak spoke about the performance of iQOS in the

Japanese market and stated, "This growth trend continued in January of 2018" while displaying a slide that showed iQOS's 16.3% national market share in Japan. *Id.* ¶¶ 129, 293; McDonough Decl. Ex. 9, at 42 ("CAGNY Presentation Slides"). He claimed, "Our weekly offtake shares in Japan continued to grow in January, both nationally and in the prefectures where the heated tobacco category is the most mature from a competitive standpoint."[2] *Id.* ¶¶ 130, 295. He also stated, "Our strong share performances for iQOS continue to be underpinned by high iQOS switching across markets . . . . The most obvious example is Japan," in a reference to switching consumers from conventional cigarettes to heated tobacco products. *Id.* ¶¶ 132, 297. Defendant King referred to the Company's iQOS performance as "remarkable." *Id.* ¶ 134.

The day after the CAGNY conference, Calantzopoulos sold 49,000 shares of his personally held Philip Morris stock for proceeds of over $5 million. *Id.* ¶¶ 138, 316, 318.

H. Defendants' Announcement About Slowing Growth in Japan and Subsequent Decline in Stock Value

On April 19, 2018, Philip Morris issued a press release announcing its first quarter 2018 financial results and revealing that contrary to its prior projections, growth in iQOS sales had slowed in Japanese markets. *Id.* ¶ 139. Specifically, Defendants announced that the Company was experiencing "less-rapid-than-initially-projected growth in sales of devices to consumers in Japan in the first quarter, as we are now reaching more conservative adult smoker segments that may require, at least at first, slightly more time for adoption." *Id.* The Company reported 6.2 billion HeatStick shipments to Japan in the first quarter of 2018—nearly 7 billion fewer HeatSticks than the Company shipped to that market in the prior quarter. *Id.* ¶ 140.

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[2] "Offtake share represents select C[onvenience]-Store sale volume for *HeatSticks* as a percentage of the total retail sales volume for cigarettes and heated tobacco units." CAC ¶ 130; CAGNY Presentation Slides at 45.

During an earnings call that day, Defendant King stated that the Company sold fewer iQOS devices in Japan than expected "due to still limited awareness of iQOS increased availability and, more importantly, to the fact that we are reaching, earlier in the year than we had anticipated, the more conservative consumers, especially the age 50-plus smoker segment, which represents approximately 40% of the total adult smoker population." *Id.* ¶ 142; McDonough Decl. Ex. 22, at 5 ("April 19, 2018 Call Tr."). He also stated that "we are now reaching different socioeconomic strata, with more conservative adult smokers who may have slightly slower patterns of adoption." CAC ¶ 142; April 19, 2018 Call Tr. at 4-5. Asked why the quarter-end result differed from the monthly market share figure provided at the February CAGNY conference, King further disclosed that the Company's market share growth in Japan had hit a "plateau," which Defendants were "anticipating" would be reached later in 2018 "given that we knew the consumer dynamic that we had—close to saturating the early adopters and innovators". *Id.* ¶ 143; April 19, 2018 Call Tr. at 8. Plaintiffs allege that Defendants had not previously communicated this dynamic to the market. CAC ¶ 143. King also stated that the January market share numbers that he and his colleagues had presented at CAGNY were "probably a little overstated" due to changes in competitors' inventory shipments. CAC ¶ 146; April 19, 2018 Call Tr. at 8. Finally, he claimed that "if this situation in Japan persists, then our volume estimate for heated tobacco units will be more in the range of 55 billion to 60 billion versus the over 60 billion that we had called out before." CAC ¶ 147; April 19, 2018 Call Tr. at 10.

Following the announcement, Philip Morris's common stock fell $15.80 per share, or more than 15%, from $101.44 per share on April 18, 2018 to close at $85.64 per share on April 19, 2018. CAC ¶¶ 13, 152. This drop represented the worst daily decline for the Company's stock in nearly a decade. *Id.* ¶ 13.

I. FDA Approves the Sale of iQOS[3]

On April 30, 2019, the FDA authorized the sale of iQOS in the United States. McDonough Decl. Ex. 2. The FDA's press release stated, "Following a rigorous science-based review . . . the agency determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes." *Id.* The FDA cautioned, however, "While today's action permits the tobacco products to be sold in the U.S., it does not mean these products are safe or 'FDA approved.'" *Id.* The FDA also stated, "[T]oday's action is not a decision on the separate modified risk tobacco product (MRTP) applications that the company also submitted for these products . . . to market them with claims of reduced exposure or reduced risk." *Id.* To this day, Philip Morris's MTRPA is still pending. *See* Defs.' MTD at 8.

II. Procedural History

On September 5, 2018, the City of Westland Police and Fire Retirement System, a purchaser of Philip Morris common stock during the Class Period, commenced this action by filing a class action complaint against Defendants Philip Morris, Calantzopoulos, King, and Olczak. Dkt. 9. On February 25, 2019, the Court appointed Union Asset Management Holding AG and Teamsters Local 710 Pension Fund as Co-Lead Plaintiffs, consolidated three related actions, and appointed Co-Lead Counsel. Dkts. 82, 83.

On May 10, 2019, Lead Plaintiffs filed a Consolidated Amended Class Action Complaint naming Defendants Picavet, Peitsch, and Lüdicke in addition to the initial defendants. Dkt. 92.

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[3] The CAC does not include any reference to the FDA's approval of the sale of iQOS, which occurred after the close of the Class Period. The Court may nonetheless consider the FDA's approval as it is information in the public domain. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 539 (S.D.N.Y. 2015) ("On a motion to dismiss, the Court may consider 'information already in the public domain and facts known or reasonably available to the shareholders.'" (quoting *Rodman v. Grant Found.*, 608 F.2d 64, 70 (2d Cir.1979))), *aff'd sub nom.*, *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

On July 12, 2019, Defendants filed a motion to dismiss Plaintiffs' Consolidated Amended Complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, and the Private Securities Litigation Reform Act. Dkts. 107-109. On September 11, 2019, Plaintiffs filed their opposition to the motion to dismiss, Dkt. 115, and on October 11, 2019, Defendants filed their reply, Dkt. 116. The Court held oral argument on November 26, 2019. Dkt. 120.

III. The Consolidated Amended Class Action Complaint

Plaintiffs have identified roughly seventy statements by Defendants they claim are false and misleading. CAC ¶¶ 155-298. According to the CAC, Defendants' allegedly false and misleading statements can be grouped into two categories: (1) statements about the clinical studies conducted in connection with Philip Morris's MRTPA to the FDA for iQOS; and (2) statements about the performance of iQOS in Japan.

A. Allegedly False and Misleading Statements About the Clinical Studies

Plaintiffs allege that Defendants repeatedly made false and misleading statements about the results of the clinical studies they conducted on iQOS and the alleged health benefits of iQOS as compared to traditional cigarettes. *See* CAC ¶¶ 156-274. For example, on a September 29, 2016 call with analysts and investors, Defendant Peitsch stated:

> In summary, the scientific research conducted across a range of studies demonstrates that IQOS has a wide array of benefits compared to smoking cigarettes. We have focused on the health effects of the product and its potential to reduce risk, on the product's environmental impact including odor and indoor air quality, and on short-term benefits such as oral hygiene . . . . Most importantly, the totality of the evidence generated to-date supports our conclusion that IQOS has the potential to reduce the risk of smoking-related diseases in adult smokers who switch to it completely.

CAC ¶ 169. Similarly, Plaintiffs allege that Defendant Picavet made false and misleading statements when he alleged, "The[] [clinical] studies show that the toxicological profile of [iQOS] in the laboratory is almost indistinguishable from conditions where no cigarette is present" and

that "[h]armful and potentially harmful compounds were reduced in [iQOS] aerosol by up to 96% compared to cigarettes." *Id.* ¶ 177. Plaintiffs allege that these statements, among others about the results of the iQOS studies and the purported health benefits of iQOS, were false and misleading because (1) some of the clinical study results were invalid due to Philip Morris's alleged failure to comply with GCP; (2) the studies suffered from other alleged deficiencies; and (3) other scientific studies conducted by Philip Morris showed that iQOS contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes. *See id.* ¶¶ 160, 170, 178, 180, 182, 186, 237, 247.

Plaintiffs also allege that Defendants repeatedly made false and misleading statements about the Company's purported compliance with GCP. For example, on September 29, 2016, the Company released Issue 1 of its Reduced-Risk Product Scientific Update Report stating, "We conduct our research in accordance with international standards and practices, such as the internationally accepted Good Laboratory Practices (GLPs) and Good Clinical Practices (GCPs)." *Id.* ¶ 173. Philip Morris made similar claims in other publicly-available reports. *See, e.g., id.* ¶¶ 167, 175, 218, 236, 240, 249, 255. Plaintiffs allege that these statements were false and misleading because the studies allegedly did not comply with GCP and suffered from other deficiencies. *See id.* ¶¶ 168, 174, 176, 219, 237, 241, 250, 256.

B. Allegedly False and Misleading Statements About Growth in Japan

Plaintiffs allege that Defendants also made false and misleading statements about sales growth in Japan. *See* CAC ¶¶ 275-298. For example, as described above, Defendant Calantzopoulos discussed "increasing demand for HeatSticks, which we expect to grow further in the first quarter [of 2018]" on a February 8, 2018 conference call with analysts and investors. *Id.* ¶¶ 123, 278. He also stated that "there's nothing in the horizon that would affect—that would cause any change in what happened in the previous years." *Id.* ¶¶ 124, 283. Plaintiffs allege that

these statements, among other related ones, were false and misleading because they failed to disclose and/or misrepresented adverse facts that Defendants knew, or recklessly disregarded, at the time they made the statements including (1) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling; (2) that the Company had saturated the younger, easier-to-convert, iQOS user base in Japan; (3) that Philip Morris was experiencing plateauing market share growth in Japan; (4) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and (5) that the shipment volume of HeatSticks to Japan was on track to decline by almost seven billion units quarter-on-quarter in the first quarter of 2018. *See id.* ¶¶ 277, 279, 281, 284, 286.

Plaintiffs also allege that Defendants made numerous false and misleading statements at the February 21, 2018 CAGNY conference. As described above, Defendant Calantzopoulos stated that Philip Morris was a "growth stock" and that "8% plus currency-neutral net revenue growth is not just a 2017 or 2018 phenomenon." *Id.* ¶¶ 128, 287. Defendant Olczak spoke about the performance of iQOS in the Japanese market and stated, "This growth trend continued in January of 2018." *Id.* ¶¶ 129, 293. He claimed, "Our weekly offtake shares in Japan continued to grow in January, both nationally and in the prefectures where the heated tobacco category is the most mature for a competitive standpoint," and represented that demand for iQOS in Japan was "anticipated to further increase in the first quarter of 2018." *Id.* ¶¶ 130, 285, 295. He also stated, "Our strong share performances for iQOS continue to be underpinned by high iQOS switching across markets . . . . The most obvious example is Japan," in a reference to switching consumers from conventional cigarettes to heated tobacco products. *Id.* ¶¶ 132, 297. Plaintiffs allege that the statements Defendants made at CAGNY were false and misleading because they failed to disclose

and/or misrepresented adverse facts that Defendants knew, or recklessly disregarded, at the time they made the statements. *See id.* ¶¶ 288, 290, 292, 294, 296, 298.

LEGAL STANDARD

I. Motions to Dismiss Under Federal Rule of Civil Procedure 12(b)(6)

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In making this determination, the Court must "accept[] all factual allegations as true, but 'giv[e] no effect to legal conclusions couched as factual allegations.'" *Stadnick*, 861 F.3d at 35 (quoting *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 321 (2d Cir. 2010)). Moreover, on a motion to dismiss, a court "may consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

II. Motions to Dismiss Under Federal Rule of Civil Procedure 9(b) and the PSLRA

Securities fraud claims must also meet the heightened pleading requirements of Rule 9(b) and the Private Securities Litigation Reform Act of 1995 (the "PSLRA"), 15 U.S.C. § 78u-4(b). *See ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. J.P. Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009). Rule 9(b) requires that a plaintiff alleging fraud "must state with particularity the circumstances constituting" the alleged fraud. Fed. R. Civ. P. 9(b). To do so successfully, "the plaintiff must '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the

statements were fraudulent.'" *Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98, 108 (2d Cir. 2012) (quoting *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004)).

The PSLRA expands on Rule 9(b) and requires "that securities fraud complaints 'specify' each misleading statement; that they set forth the facts 'on which [a] belief' that a statement is misleading was 'formed'; and that they 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Anschutz Corp.*, 690 F.3d at 108 (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345 (2005)). Nevertheless, "even with the heightened pleading standards of Rule 9(b) and the PSLRA, the Court '[does] not require the pleading of detailed evidentiary matter[s] in securities litigation.'" *Galestan v. OneMain Holdings, Inc.*, 348 F. Supp. 3d 282, 302 (S.D.N.Y. 2018) (quoting *New Orleans Emps. Ret. Sys. v. Celestica, Inc.*, 455 F. App'x 10, 15 (2d Cir. 2011)).

DISCUSSION

Plaintiffs bring two claims under the Exchange Act. First, they allege that Defendants violated § 10(b) and Rule 10b–5 promulgated thereunder because they made false and misleading statements about clinical trials Philip Morris conducted in connection with its Modified Risk Tobacco Product Application to the U.S. Food and Drug Administration, as well as false and misleading statements about the performance of its reduced risk products in Japan. CAC ¶¶ 344-48. Second, Plaintiffs allege that the Individual Defendants are liable pursuant to § 20(a) of the Exchange Act because they controlled the § 10(b) violators. *Id.* ¶¶ 349-50. The Court will consider each claim in turn.

I. Section 10(b) and Rule 10b-5 of the Securities Exchange Act

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff "must prove (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the

misrepresentation or omission; (5) economic loss; and (6) loss causation." *Pac Inv. Mgmt. Co. v. Mayer Brown LLP*, 603 F.3d 144, 151 (2d Cir. 2010) (quoting *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). Because Defendants only challenge the first and second factors in their motion, the Court addresses only those factors in its Opinion.

A. Whether Plaintiffs Adequately Allege That Defendants Were Responsible for False or Misleading Statements of Material Fact

As described above, Plaintiffs allege that Defendants made false and misleading statements throughout the Class Period regarding (1) the clinical trials Philip Morris conducted in connection with its MRTPA to the FDA for iQOS; and (2) the performance of iQOS in Japan. Under Rule 10b-5, it is unlawful to (1) "make any untrue statement of a material fact," or (2) "omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). In other words, to support a finding of liability under Rule 10b-5, there must be "an actual *statement*, one that is either 'untrue' outright or 'misleading' by virtue of what it omits to state" or a "complete failure to make a statement" in circumstances "when the corporation is subject to a duty to disclose the omitted facts." *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 239 (2d Cir. 2016) (citations omitted). Thus, the "starting point for any 10b-5 case is the existence of material misstatements or omissions of fact." *In re MBIA, Inc., Sec. Litig.*, 700 F. Supp. 2d 566, 578 (S.D.N.Y. 2010).

For a statement of fact to be actionable under Section 10(b), "the statement must be false, and the statement must be material. Neither immaterial false statements nor material true statements are actionable." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)). As to falsity, a claim for securities fraud premised on a misstatement "cannot occur unless an alleged material misstatement was false *at the time it was made*." *Id.* Thus, "[a] statement believed to be true when made, but later shown to

be false, is insufficient." *Id.* Moreover, the Second Circuit has repeatedly stated that plaintiffs must do more than simply assert that a particular statement is false or misleading; rather, "they must demonstrate with specificity why and how that is so." *Rombach*, 355 F.3d at 174. As to materiality, "there must be a substantial likelihood that a reasonable person would consider the fact misstated or omitted important in connection with a contemplated securities transaction." *In re Lululemon*, 14 F. Supp. 3d at 572; *see also Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 181 (S.D.N.Y. 2010). However, "whether a reasonable investor would find a particular misrepresentation or omission material to an investment decision is usually a matter reserved for the trier of fact." *In re Inv. Tech. Grp., Inc. Sec. Litig.*, 251 F. Supp. 3d 596, 609 (S.D.N.Y. 2017). Therefore, "a complaint may not properly be dismissed . . . on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 162 (2d Cir. 2000).

A Section 10(b) claim premised on an omission is "actionable under the securities laws only when the corporation is subject to a duty to disclose the omitted facts." *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 101 (2d Cir. 2015). "The law is well settled, however, that so-called 'half-truths'—literally true statements that create a materially misleading impression—will support claims for securities fraud." *SEC v. Gabelli*, 653 F.3d 49, 57 (2d Cir. 2011), *rev'd on other grounds, Gabelli v. SEC*, 568 U.S. 442 (2013); *see also In re MBIA*, 700 F. Supp. 2d at 578 ("A statement can [] be misleading, though not technically false, if it amounts to a half-truth by omitting some material fact.") (quoting *In re Nokia Oyj (Nokia Corp.) Sec. Litig.*, 423 F. Supp. 2d 364, 393 (S.D.N.Y. 2006)).

Defendants argue that Plaintiffs have not adequately alleged that any of the statements in

the CAC were false or misleading. The Court agrees. Some of the statements in the CAC were in fact true statements at the time they were made. Others are inactionable because they amount to puffery, subjective statements of opinion, or forward-looking statements. The Court considers each of these categories of statements in turn.

i. True Statements

First, Plaintiffs fail to allege sufficient facts establishing that a number of the statements were false or misleading when they were made. It is "well settled that a complaint alleging violations of the securities laws may not rely upon statements that are true." *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004). Plaintiffs repeatedly allege that the following statement made by Philip Morris in its Forms 10-Ks and Form 10-Qs in 2015, 2016, and 2017 was false and misleading: "We may be unsuccessful in our attempts to introduce reduced-risk products, and regulators may not permit the commercialization of these products or the communication of scientifically substantiated risk-reduction claims." CAC ¶¶ 163, 194, 202, 213, 235, 245, 273. Far from being false or misleading, however, this statement was a truthful expression of Philip Morris's lack of certainty that the FDA would approve its MTRPA. If anything, this statement demonstrates that Defendants explicitly communicated to investors the possibility that iQOS would not clear regulatory hurdles.

Defendant Picavet's statement that "a few [study] participants produced an excessive quantity of urine in a 24-hour period, which is quite uncommon" and that, following an audit, the principal investigator "decided to mark these incidents as adverse events and to monitor consumption of water for the remaining participants" is also a true statement. CAC ¶ 257; McDonough Decl. Ex. 26, at 4. Plaintiffs allege that this statement was false and misleading because, *inter alia*, it "failed to disclose that the individuals produced urine samples of 12-18 liters, an impossible amount of urine a human being can produce, as normal urine samples produced by

humans are between 2-4 liters." CAC ¶ 258. Plaintiffs, however, attempt to hold Defendants to an impossible standard that is divorced from the dictates of the securities laws. Picavet's statement is not rendered false or misleading simply because he described the quantity of urine as "excessive" rather than specifying that the urine samples were 12-18 liters.

ii. Inactionable Puffery

A statement of "puffery," i.e. "an optimistic statement that is so vague, broad, and non-specific that a reasonable investor would not rely on it," is not actionable. *Galestan*, 348 F. Supp. 3d at 297-98; *see Novak v. Kasaks*, 216 F.3d 300, 315 (2d Cir. 2000) (noting that "statements containing simple economic projections, expressions of optimism, and other puffery are insufficient"); *In re Lululemon*, 14 F. Supp. 3d at 572 (noting that "[r]osy predictions, or statements that are loosely optimistic regarding a company's well-being" are "too vague and general to be actionable" under the securities laws); *see also Galestan*, 348 F. Supp. 3d at 298 (explaining that the rule regarding puffery "permits companies 'to operate with a hopeful outlook,' because corporate officers 'are not required to take a gloomy, fearful or defeatist view of the future'") (quoting *Rombach*, 355 F.3d at 174). Notwithstanding the rule against puffery, statements regarding "projections of future performance may be actionable . . . if they are worded as guarantees or are supported by specific statements of fact, or if the speaker does not genuinely or reasonably believe them." *In re IBM Corp. Sec. Litig.*, 163 F.3d 102, 107 (2d Cir. 1998) (citations omitted); *see also Jiehua Huang v. AirMedia Grp. Inc.*, No. 15-CV-04966, 2017 WL 1157134, at *8 (S.D.N.Y. Mar. 27, 2017).

A number of the challenged statements identified in the CAC are mere puffery. For example, Philip Morris's statements that it was "conducting extensive and rigorous scientific studies," "conduct[ing] rigorous scientific assessment[s]," "draw[ing] upon a team of world-class scientists," following a "thorough and systematic approach to smoke-free product development

and assessment," "following a rigorous scientific assessment program," "draw[ing] upon a team of expert scientists," and conducting "research [that] meets rigorous standards" are mere puffery. CAC ¶¶ 157, 183, 188, 198, 209, 231, 240, 243, 262, 271. Calantzopoulos's statement that "I think we are producing the best science you can produce in the field today" is also puffery, *id.* ¶¶ 165, 195, 268, as is Philip Morris's statement that its "studies are very advanced and point in the direction of risk reduction and potential to improve public health." *Id.* ¶¶ 216, 246, 253. "[T]hese statements did not, and could not, amount to a guarantee" regarding the quality of Philip Morris's studies or the likelihood of FDA approval. *ECA*, 553 F.3d at 206 (holding statements about "highly disciplined" risk management processes and standard-setting reputation for integrity were merely puffery). Instead, these statements were "too general to cause a reasonable investor to rely upon them." *Id.*

iii. Statements of Opinion or Belief

In addition to objective statements or omissions of material fact, "subjective statements of opinion" may also give rise to liability under Section 10(b) in "two distinct ways." *Lopez v. CTPartners Executive Search Inc.*, 173 F. Supp. 3d 12, 23 (S.D.N.Y. 2016). The Supreme Court articulated the standards governing opinion statements in *Omnicare, Inc., et al., v. Laborers District Council Construction Industry Pension Fund, et al.*, 575 U.S. 175 (2015), and the Second Circuit applied them in the context of a defendant company's statements about an application pending before the FDA in *Tongue v. Sanofi,* 816 F.3d 199, 210 (2d Cir. 2016). First, "liability for making a false statement of opinion may lie if either 'the speaker did not hold the belief she professed' or 'the supporting fact[s] she supplied were untrue.'" *Sanofi*, 816 F.3d at 210 (quoting *Omnicare*, 575 U.S. at 186). However, "a sincere statement of pure opinion is not an 'untrue statement of material fact,' regardless whether an investor can ultimately prove the believe wrong." *Omnicare*, 575 U.S. at 186. As the Second Circuit "has firmly rejected [the] 'fraud by hindsight'

approach" it is "not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, [or] not borne out by subsequent events." *Lopez*, 173 F. Supp. 3d at 24 (citations omitted).

Second, "opinions, though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information whose omission makes the statement misleading to a reasonable investor." *Id.* (quoting *Sanofi*, 816 F.3d at 210). A reasonable investor "expects not just that the [speaker] believes the opinion (however irrationally), but that it fairly aligns with the information in the [speaker's] possession at the time." *Omnicare*, 575 U.S. at 188-89. To sufficiently allege that a statement of opinion was false or misleading through the omission of material information, a plaintiff "must identify particular (and material) facts going to the basis for the [speaker's] opinion—facts about the inquiry the [speaker] did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *Sanofi*, 816 F.3d at 209 (quoting *Omnicare*, 575 U.S. at 194). The "core inquiry" is thus "whether the omitted facts would 'conflict with what a reasonable investor would take from the statement itself.'" *Id.* at 210 (quoting *Omnicare*, 575 U.S. at 189). The Supreme Court, however, has "cautioned against an overly expansive reading of this standard, noting that '[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts,' and adding that '[a] reasonable investor does not expect that *every* fact known to [a speaker] supports its opinion statement.'" *Id.* (quoting *Omnicare*, 575 U.S. at 189-90). Therefore, "a statement of opinion 'is not necessarily misleading when [a speaker] knows, but fails to disclose, some fact cutting the other way.'" *Id.* (quoting *Omnicare*, 575 U.S. at 189). "Moreover, whether an omission makes an expression of opinion misleading always depends on context . . . . So an omission that renders misleading a

statement of opinion when viewed in a vacuum may not do so once that statement is considered, as is appropriate, in a broader frame." *Omnicare*, 575 U.S. at 190.

Much like this case, *Tongue v. Sanofi*, 816 F.3d 199 (2d. Cir 2016), involved a company's alleged misstatements regarding the methodology it used in clinical trials, the results of those trials, and the likelihood of obtaining FDA approval of the company's product—in that case, a multiple sclerosis drug. The Second Circuit held that the company "need not have disclosed" the FDA's critique of its clinical trial methodology "merely because it tended to cut against their projections" of FDA approval, as "Plaintiffs were not entitled to so much information as might have been desired to make their own determination about the likelihood of FDA approval." *Id.* at 212. With respect to the defendants' claims about clinical trial results, the Second Circuit held that the "Defendants' statements about the effectiveness of [the drug] cannot be misleading merely because the FDA disagreed with the conclusion—so long as Defendants conducted a 'meaningful' inquiry and in fact held that view, the statements did not mislead in a manner that is actionable." *Id.* at 214. In so doing, the court determined that the plaintiffs' claim that the defendants misled investors by making positive statements about the results of the trials amounted to "little more than a dispute about the proper interpretation of data." *Id.* It further noted that "no sophisticated investor familiar with standard FDA practice would expect that every view of the data taken by Defendants was shared by the FDA." *Id.*

The Court agrees with Defendants that Plaintiffs have failed to allege any omission that would make Defendants' opinion statements about its clinical studies misleading to a reasonable investor under the standards set forth in *Sanofi*. For example, Defendant Picavet's statement that "the totality-of-the evidence collected to date is very encouraging, in terms of individual risk reduction potential and harm reduction on a population level," is a mere "generalized statement of

subjective optimism" that would not have misled a reasonable investor. CAC ¶ 185; *Sanofi*, 816 F.3d at 213; *see also* CAC ¶ 169 (similar statement by Defendant Peitsch). Further, just as the defendants' statement that their data demonstrated a "strong and robust treatment effect" was inactionable in *Sanofi*, *see* 816 F.3d at 213, so too are Philip Morris's statements that its "study results show a substantial reduction in relevant biomarkers of exposure to harmful or potentially harmful constitutions."[4] CAC ¶¶ 159, 190, 200, 211, 233; *see also* CAC ¶¶ 177, 179, 181, 204, 206, 214, 218, 221, 223, 225-228, 238, 248, 251, 264, 266 (additional statements about the results of scientific studies). Moreover, Defendants' statements about the results of its clinical studies were not misleading "merely because the [TPSAC] disagreed with the conclusion," as "no sophisticated investor familiar with standard FDA practice would expect that every view of the data taken by Defendants was shared by the FDA." *Sanofi*, 816 F.3d at 214. Rather, Defendants' statements appear to be supported by their "meaningful inquiry" into the health benefits of iQOS. *Id.* Accordingly, like in *Sanofi*, Plaintiffs' argument amounts to "little more than a dispute about the proper interpretation of data." *Sanofi*, 816 F.3d at 214; *see also Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013) ("[W]here a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement.").[5]

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[4] Defendants also argue that their statements about clinical studies were not false or misleading in light of the fact that the TPSAC—armed with all of the data from Philip Morris's studies, including the four studies that were belatedly disclosed—voted overwhelmingly that "[s]cientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals," despite rejecting Philip Morris's claims about reduced risk. *See* Defs.' MTD at 14-15; McDonough Decl. Ex. 15. The Court agrees that the TPSAC vote on Defendants' reduced exposure claim undercuts Plaintiffs' argument that Defendants' statements about reduced exposure were false or misleading.

[5] Defendants also argue that their statements about clinical studies were not false or misleading given that the FDA authorized the sale of iQOS in the United States and issued a press release stating, "Following a rigorous science-based review . . . the agency determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes." McDonough

Defendants' statements that they complied with GCP were also not false or misleading for substantially the same reasons. *See* CAC ¶¶ 167, 173, 175, 218, 236, 240, 249, 255, 259, 260. *Sanofi* makes clear that a corporate defendant need not disclose all concerns about its research methodology so long as the omitted facts do not "conflict with what a reasonable investor would take from the statement itself." 816 F.3d at 211 (quoting *Omnicare*, 575 U.S. at 189). In *Sanofi*, the FDA itself repeatedly expressed concerns regarding the defendants' research methodology, yet the court still held that the defendants' failure to disclose the FDA's concerns did not render their statements regarding expected FDA approval false or misleading. *Id.* at 211-13. Here, the FDA has not expressed any concerns regarding Defendants' research methodology or questioned whether Philip Morris complied with GCP. Instead, Plaintiffs point to concerns raised by Tamara Koval and other scientists who were interviewed in the *Reuters* article. Defendants' failure to inform investors about the alleged methodological flaws in its studies did not render any of its statements about compliance with GCP false or misleading "merely because it tend[s] to cut against" the claim of compliance. *Id.* at 212. Additionally, the statements about Philip Morris's "rigorous" standards and team of "expert scientists" identified above as puffery also constitute inactionable statements of opinion.

Finally, Plaintiffs allege that Defendants failed to disclose the results of four adverse studies in a timely fashion. CAC ¶¶ 85-89. These allegations suggest that Philip Morris may not have been acting with complete transparency and thus come closest to representing a material

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Decl. Ex. 2. The FDA cautioned, however, that its authorization of the sale of iQOS "is not a decision on the separate modified risk tobacco product (MRTP) applications," which remains pending. The Court need not—and does not—reach a conclusion as to whether the FDA's authorization of the sale of iQOS has any bearing on the truthfulness of Philip Morris's statements about reduced risk.

omission.[6] However, as the Second Circuit has held, a corporate defendant "need not have disclosed" all negative facts that "tended to cut against their projections" of FDA approval, as "Plaintiffs were not entitled to so much information as might have been desired to make their own determination about the likelihood of FDA approval." *Sanofi*, 816 F.3d at 212. As in *Sanofi*, "Plaintiffs would have been interested in knowing" about the adverse studies earlier, "and perhaps would have acted otherwise had the [adverse studies] been disclosed, but *Omnicare* does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion." *Id.* Moreover, Plaintiffs fail to plead with particularity *how* Defendants' alleged failure to disclose the four studies in a timely fashion rendered any of its statements "misleading to a reasonable person reading the statement fairly and in context." *Omnicare*, 575 U.S. at 194. Instead, Plaintiffs repeatedly assert that a wide range of Defendants' statements connected to its scientific studies were false and misleading for failure to disclose that "other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes," even when they challenged statements that made no mention of the comparative incidence of toxicological compounds in iQOS versus conventional cigarettes. *See, e.g.*, CAC ¶ 170.

Because it is possible that, if given the opportunity to re-plead, Plaintiffs could assert facts

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[6] For example, Philip Morris's 2016 Form 10-K, filed with the SEC on February 14, 2017, stated: "Eight clinical studies have been completed (including two with the duration of three months). The study results show a substantial reduction in relevant biomarkers of exposure to harmful or potentially harmful constituents ("HPHCs") in those adult smokers who switched to IQOS compared to those who continued to smoke cigarettes for the duration of the study." CAC ¶ 200; McDonough Decl. ¶ 35; McDonough Decl. Ex. 33. However, it appears that *twelve* clinical studies had been completed by February 14, 2017, *six* of which had a duration of three months: two of the disclosed studies, two of the undisclosed studies that covered the period of March 2016 through June 2016, and two of the undisclosed studies that covered the period of October 2016 through January 2017. CAC ¶¶ 51, 85. Further, Plaintiff alleges that all four undisclosed studies demonstrated that 17-18 of the FDA's list of 93 HPHCs were present at the same elevation in iQOS as in conventional cigarettes, and that the studies were silent on the remaining 76-77 HPHCs. *Id.* ¶¶ 87-88.

plausibly supporting their claims related to Defendants' failure to timely disclose the four studies, dismissal of these claims is without prejudice. *See* Fed. R. Civ. P. 15(a)(2) ("The court should freely give leave when justice so requires."). If Plaintiffs re-pleads these claims, however, they must do more than simply assert that Defendants' claims about its scientific studies were false or misleading given the existence of other, undisclosed studies. Rather, "they must demonstrate with specificity why and how that is so," *Rombach*, 355 F.3d at 174, including by explaining how the results of the undisclosed studies undercut the truthfulness of Defendants' statements about reduced risk and/or reduced exposure.

In sum, Plaintiffs have failed to adequately allege that Defendants withheld material facts that made their statements about the results of their clinical studies and compliance with GCP misleading to a reasonable investor. Moreover, Plaintiffs have not alleged that Defendants "did not hold the belief [they] professed" about the results of the studies or their compliance with GCP, or that they supplied "supporting fact[s]" that were "untrue" under the alternative *Omnicare* prong. 575 U.S. at 186. However, because the Court finds Plaintiffs' claims with respect to the four undisclosed studies present a closer question, those claims are dismissed without prejudice.

iv. Forward-Looking Statements Under the PSLRA

A number of Defendants' alleged misstatements fall under the PSLRA's safe harbor for "forward looking statements." *See* 15 U.S.C. § 78u-5. As a general rule, forward-looking statements are "statements whose truth cannot be ascertained until some time after they are made." *In re Vale S.A. Sec. Litig.*, No. 15-CV-9539 (GHW), 2017 WL 1102666, at *24 (S.D.N.Y. Mar. 23, 2017) (quoting *In re Bear Stearns Cos., Inc. Sec., Derivative, and ERISA Litig.*, 763 F. Supp. 2d 423, 493 (S.D.N.Y. 2011)). The PSLRA specifically defines "forward-looking statements" as those that contain, among other things, "the plans and objectives of management for future operations," "future economic performance," and "a projection of revenues, income . . . , [or]

earnings." 15 U.S.C. § 78u-5(i)(1).

Under the PSLRA's safe harbor, a defendant "shall not be liable with respect to any forward-looking statement" if (1) the forward-looking statement is "identified" as such and "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement," or (2) the forward-looking statement is "immaterial," or (3) the plaintiff "fails to prove that the forward-looking statement . . . if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1). "Because the statute is written in the disjunctive, statements are protected by the safe harbor if they satisfy any one of these three categories." *Lopez*, 173 F. Supp. 3d at 25 (citing *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010)); *see also In re WEBMD Health Corp. Sec. Litig.*, No. 11-CV-5382 (JFK), 2013 WL 64511, at *7 (S.D.N.Y. Jan. 2, 2013).[7]

To fall within the "meaningful cautionary statements" prong of the safe harbor, the cautionary language "must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements." *Slayton*, 604 F.3d at 771. In other words, "defendants must demonstrate that their cautionary language was not boilerplate and conveyed substantive information." *Id.* at 772; *see also In re Salix Pharmaceuticals, Ltd.*, No. 14-CV-8925 (KMW), 2016 WL 1629341, at *11 (S.D.N.Y. Apr. 22, 2016) ("Vague disclosures of general risks will not protect defendants from liability.") (quoting *In*

[7] Similarly, the judicially-created "'bespeaks caution' doctrine generally protects forward-looking statements that adequately disclose the risk factors that might cause a different outcome to occur than the one then forecast by the issuer." *Lopez*, 173 F. Supp. 3d at 39 (citing *Iowa Pub. Emps. Ret. Sys. v. MF Global, Ltd.*, 620 F.3d 137, 141 (2d Cir. 2010) ("*Iowa Pub.*")). This doctrine provides that a "forward-looking statement accompanied by sufficient cautionary language is not actionable because no reasonable investor could have found the statement materially misleading." *Iowa Pub.*, 620 F.3d at 141. "In such circumstances, it cannot be supposed by a reasonable investor that the future is settled, or unattended by contingency." *Id.*

re MF Global Holdings Ltd. Sec. Litig., 982 F. Supp. 2d 277, 304 (S.D.N.Y. 2013)); *Lopez*, 173 F. Supp. 3d at 25 ("Plaintiffs may establish that cautionary language is not meaningful 'by showing, for example, that the cautionary language did not expressly warn of or did not directly relate to the risk that brought about plaintiffs' loss.'") (quoting *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002)).

The PSLRA safe harbor also "specifies an 'actual knowledge' standard for forward-looking statements," which means that "the scienter requirement for forward-looking statements is stricter than for statements of current fact. Whereas liability for the latter requires a showing of either knowing falsity or recklessness, liability for the former attaches only upon proof of knowing falsity." *Slayton*, 604 F.3d at 773 (citations omitted). For a forward-looking statement to be actionable, the plaintiff must show that the statement was "made with actual knowledge of [its] falsity by the speaker." *In re Salix*, 2016 WL 1629341, at *9 (citing 15 U.S.C. § 78u-5(c)(1)(B)(i)-(ii)).

A number of Defendants' alleged misstatements about growth in Japan fall within the first prong of the safe harbor for forward-looking statements. For example, Defendant Calantzopoulos's statement in Philip Morris's February 8, 2018 press release that "[c]ontinued investment behind IQOS in 2018 is expected to further drive its positive momentum" is an inactionable forward-looking statement. CAC ¶ 276; McDonough Decl. Ex. 20 at 3. First, the February 8, 2018 press release identified the statement as forward looking. It stated, "This press release contains projections of future results and other forward-looking statements. Achievement of future results is subject to risks, uncertainties and inaccurate assumptions . . . . [A]ctual results could vary materially from those contained in such forward-looking statements." McDonough Decl. Ex. 20 at 31. Second, the statement was accompanied by meaningful cautionary language

that "was not boilerplate and conveyed substantive information." *Slayton*, 604 F.3d at 771. The press release identified Philip Morris's business risks as including "increasing marketing and regulatory restrictions," "health concerns relating to the use of tobacco products," and "changes in adult smoker behavior." McDonough Decl. Ex. 20 at 31. It also stated, "PMI's future profitability may also be adversely affected should it be unsuccessful in its attempts to produce and commercialize reduced-risk products or if regulation or taxation do not differentiate between such products and cigarettes." *Id.*

Defendant Calantzopoulos also referenced the cautionary statements in the February 8, 2018 press release during the earnings call that day. *See* McDonough Decl. Ex. 19, at 6 ("I direct your attention to the forward-looking and cautionary statements disclosure in today's presentation and press release for a review of the various factors that could cause actual results to differ materially from projections or forward-looking statements."). During that call, he made additional forward-looking statements, including the claim that "there's nothing in the horizon that would affect—that would cause any change in what happened in the previous years." CAC ¶ 283; *see also id.* ¶¶ 278, 280. In light of Defendant Calantzopoulos's reference to the cautionary statement and risk factors, his statements during the February 18, 2018 call were also protected under the first prong of the safe harbor.

The statements in Philip Morris's 2017 Form 10-K, which was signed by Defendants Calantzopoulos and King, are likewise inactionable forward-looking statements. *See* CAC ¶ 285; McDonough Decl. Ex. 3, at 24. The 10-K stated that the demand for HeatSticks was "anticipated to further increase in the first quarter of 2018." CAC ¶ 285; McDonough Decl. Ex. 3, at 24. However, the 10-K included a disclaimer that it may include forward-looking statements identifiable by the use of certain words such as "anticipates," "expects," "believes," "estimates,"

"intends," "projects," "goals," or "targets." McDonough Decl. Ex. 3. The 10-K also included meaningful cautionary language that the Company "cannot guarantee that any forward-looking statement will be realized," and identified specific risk factors including "governmental action aimed at increasing regulatory requirements with the goal of reducing or preventing the use of tobacco products," "failure to compete effectively" and failure to "anticipate changes in consumer preferences." *Id.* at 7-9. Additionally, the 10-K provided that "[t]o be successful, we must . . . convince adult smokers to covert to our RRPs." *Id.* at 9.[8] These disclaimers constitute "meaningful cautionary statements" because they "convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements." *Slayton*, 604 F.3d at 771.

The aforementioned forward-looking statements are also protected under the PLSRA for the independent reason that Plaintiffs have failed to establish that they were made with "actual knowledge by [the speaker] that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(B). "In evaluating forward-looking statements (as opposed to statements of current fact), a inference of mere recklessness is not enough." *In re WEBMD*, 2013 WL 64511, at *7. As described further below, Plaintiffs have failed to establish scienter under a recklessness standard. Therefore, they necessarily fail to establish actual knowledge.

v. CAGNY

Lastly, Defendants' statements at CAGNY are inactionable for a combination of the aforementioned reasons. First, Plaintiffs fail to establish that some of the statements that

[8] Defendants' identification of these risks also defeats Plaintiffs' claim of a violation of Items 303 and 503 of Regulation S-K, 17 C.F.R. §§ 229.303, 229.503, which requires the disclosure of matters that make an investment risky. *See Ong v. Chipotle Mexican Grill, Inc.*, 2017 WL 933108, at *10 (S.D.N.Y. Mar. 8, 2017).

Defendants made at CAGNY were false or misleading when made. For example, Plaintiffs fail to establish the falsity of the following statement of Defendant Olczak: "As the understanding of the category and its benefits are established in adult smoker communities, iQOS starts enjoying word of mouth, as adult smokers share experiences with friends and peers. Although this varies according to countries and cultures, it is universally true." CAC ¶ 289. The fact that Philip Morris later revealed that the Company was experiencing "less-rapid-than-initially-projected growth in sales of devices to consumers in Japan in the first quarter, as we are now reaching more conservative adult smoker segments that may require, at least at first, slightly more time for adoption" does not render the statement at CAGNY false. *Id.* ¶ 139. Instead, iQOS could still enjoy "word of mouth" among adults even if the conservative adult smokers required slightly more time for adoption, leading to less-rapid-than-initially-projected growth in sales. Similarly, Plaintiffs fail to adequately plead the falsity of Olczak's statement, "For 2018, our priority is to go deeper with iQOS into our existing launch markets." *Id.* ¶ 291. There is no reason to conclude that Olczak misrepresented the Company's priority simply because sales grew less rapidly than initially projected in Japan in the first quarter. As the Second Circuit has held, "misguided optimism is not a cause of action, and does not support an inference of fraud. We have rejected the legitimacy of 'alleging fraud by hindsight.'" *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994) (citation omitted).

Second, some of Defendants' alleged misstatements at CAGNY constitute statements of opinion and/or puffery. For example, Defendant Calantzopoulos's statement, "Today, I believe we are exhibiting more of the attributes of a growth stock as well [as a value stock]" is a statement of opinion and puffery, as it was framed as a vague "belief" rather than a guarantee or statement of fact. CAC ¶ 287; McDonough Dec. Ex. 18, at 12. The Court is not persuaded that any

reasonable investor would rely upon this statement or similar ones. Again, because the Second Circuit "has firmly rejected [the] 'fraud by hindsight' approach," it is "not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, [or] not borne out by subsequent events." *Lopez*, 173 F. Supp. 3d at 24 (citations omitted).

Finally, Plaintiffs challenge Defendants' statements at CAGNY that (i) the iQOS market share "growth trend continued in January of 2018"; (ii) "weekly offtake shares in Japan continued to grow in January"; and (iii) "[o]ur strong share performances for iQOS continue to be underpinned by high IQOS switching across markets" (i.e., switching from traditional cigarettes to iQOSs). CAC ¶¶ 293, 295, 297. Plaintiffs allege that these statements are false and misleading in light of the April 19, 2018 revelation that the Company's market share growth had hit a "plateau," which Defendants were "anticipating" would be reached later in 2018 "given that we knew the consumer dynamic that we had—close to saturating the early adopters and innovators," and that the January market share numbers presented at CAGNY were "probably a little overstated" due to changes in competitors' inventory shipments. *Id.* ¶¶ 143, 146; April 19, 2018 Call Tr. at 8. Again, "these allegations amount to 'fraud by hindsight' because Plaintiffs plead no facts demonstrating that the Company did not actually believe" these statements when they were made. *Waterford Twp. Police & Fire Ret. Sys. v. Reg'l Mgmt. Corp.*, 723 F. App'x 20, 22 (2d Cir. 2018) (citation omitted).

B. Whether Plaintiffs Adequately Allege Scienter

Defendants also argue that the CAC must be dismissed for the independent reason that Plaintiffs have failed to sufficiently plead that any Defendant acted with the requisite scienter. The Court agrees. "Scienter is the mental state embracing an intent to deceive, manipulate, or defraud by the maker of a statement." *In re Lululemon*, 14 F. Supp. 3d at 573 (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007)). The "scienter requirement is met where the

complaint alleges facts showing" either (1) "a motive and opportunity to commit the fraud," or (2) "strong circumstantial evidence of conscious misbehavior or recklessness." *Emps. Ret. Sys. of Gov't of the Virgin Islands v. Blanford*, 794 F.3d 297, 306 (2d Cir. 2015); *see also Kalnit v. Eichler*, 264 F.3d 131, 138 (2d Cir. 2001). To adequately plead that the statements were made with the requisite scienter, plaintiffs must plead facts that "taken together give rise to a strong inference that the makers of the statements . . . knew that their statements were false or misleading when made, or recklessly disregarded that possibility." *In re Lululemon*, 14 F. Supp. 3d at 581 (citing *Tellabs* 551 U.S. at 323-24 and *Novak*, 216 F. 3d at 308-09); *see also In re Inv. Tech. Grp., Inc. Sec. Litig.*, 251 F. Supp. 3d at 620 (plaintiffs may establish scienter where they have "specifically alleged" that the "defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation") (quoting *Novak*, 216 F. 3d at 308). The relevant inquiry is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 323.

At the motion to dismiss stage, "[t]o determine whether the plaintiff has alleged facts that give rise to the requisite 'strong inference' of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs*, 551 U.S. at 323-24. "In other words, it is not enough to set out facts from which, if true, a reasonable person *could* infer that the defendant acted with the required intent." *In re Advanced Battery Techs., Inc.*, 781 F.3d 638, 644 (2d Cir. 2015) (internal quotation marks and citations omitted). Rather, the scienter requirement is met "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. The court must therefore ask: "When the

allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?" *ECA*, 553 F.3d at 198 (quoting *Tellabs*, 551 U.S. at 326). The PSLRA likewise requires that a plaintiff "state with particularity facts giving rise to a strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2)(A).

i. Plaintiffs Fail to Establish the Individual Defendants' Scienter Based on Motive and Opportunity

To satisfy the "motive and opportunity" test, a plaintiff must show that the defendant "benefitted in some concrete and personal way from the purported fraud." *Novak*, 216 F.3d at 307-08. "General allegations that defendants acted in their economic self-interest are not enough." *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009). Plaintiffs argue that two stock sales by Defendant Calantzopoulos support an inference of scienter. CAC ¶¶ 316-20. First, Plaintiffs point to Calantzopoulos's sale of 35,000 shares of his personally held Philip Morris stock for proceeds of nearly $3.6 million on February 15, 2017, the day after Philip Morris filed its Form 2016 10-K, which stated, *inter alia*, that the results from the iQOS studies "are generally consistent with the expected direction of change and indicate that switching completely to IQOS led to an overall improvement of clinical risk markers affected by smoking after only three months." *Id.* ¶ 317. Second, Plaintiffs point to Calantzopoulos's sale of 49,000 shares of his personally held Philip Morris stock for proceeds of over $5 million on February 22, 2019, the day after he and Defendants King and Olczak presented at the CAGNY conference. *Id.* ¶ 318. Plaintiffs argue that these sales were timed to capitalize on Philip Morris's inflated stock price before Philip Morris revealed the news to shareholders that the iQOS market share growth in Japan was actually plateauing in the first quarter of 2018. *Id.* ¶ 320.

Plaintiffs' allegations fail to establish a strong inference of scienter based on the above stock sales. "[T]he mere fact that insider stock sales occurred does not suffice to establish scienter.

Rather, to satisfy this element, Plaintiffs must establish that the sales were unusual or suspicious." *In re Gildan Activewear*, 636 F. Supp. 2d at 270. As Defendants explain, "the public record clearly demonstrates that Mr. Calantzopoulos followed consistent patterns of trading, did not make outsized trades during the Class Period, and his [Philip Morris] shareholdings actually *increased* throughout the Class Period. Specifically, he sold 7-8% of his total non-deferred shares *every* February from 2015 through 2019, including the two Class Period sales Plaintiffs identify in 2017 and 2018." Defs.' MTD at 28; App. B; McDonough Decl. Ex. 41. The Court agrees with Defendants that, in light of Calantzopoulos's regular trading activity, Plaintiffs fail to establish that he engaged in unusual or suspicious sales. Plaintiffs' only other allegations regarding trading of stock involve non-Defendants. Plaintiffs therefore fail to establish scienter based on the motive and opportunity theory.

ii. Plaintiffs Fail to Establish Scienter Based on Circumstantial Evidence of Conscious Misbehavior or Recklessness

Absent a showing of motive, plaintiffs may demonstrate scienter under the "strong circumstantial evidence" test, but "the strength of the circumstantial allegations must be correspondingly greater." *ECA,* 553 F.3d at 199 (quoting *Kalnit*, 264 F.3d at 142). The circumstantial evidence that can support an inference of conscious misbehavior or recklessness includes situations in which defendants: "(1) benefitted in a concrete and personal way from the purported fraud; (2) engaged in deliberately illegal behavior; (3) knew facts or had access to information suggesting that their public statements were not accurate; or (4) failed to check information they had a duty to monitor." *Id.* (quoting *Novak*, 216 F.3d at 311). Under Second Circuit case law, the recklessness required to plead scienter under this test "mean[s] 'conscious recklessness—i.e., a state of mind *approximating actual intent*, and *not merely a heightened form of negligence*.'" *S. Cherry St., LLC v. Hennessee Group LLC*, 573 F.3d 98, 109 (S.D.N.Y. 2009)

(quoting *Novak*, 216 F.3d at 312).

Plaintiffs fail to adequately support their claim that the Defendants knew, or recklessly disregarded, that their statements regarding the results of their clinical studies and compliance with GCP were false or misleading. The CAC principally relies on allegations made by Tamara Koval and statements in the *Reuters* article regarding the clinical studies. Yet Defendants rightly point out that Koval was terminated in January 2015—over 18 months before the start of the Class Period, and almost two years prior to Philip Morris's submission of its MTPRA. CAC ¶¶ 62, 81. Moreover, Koval's personal interactions with the Individual Defendants appear to have been quite limited, other than her alleged conversation with Defendant Picavet about the unusually large urine samples in the Poland study. *Id.* ¶ 81. The CAC thus fails to state with particularity facts giving rise to a strong inference that Defendants knew or recklessly disregarded the vast majority of the alleged clinical trial deficiencies reported in the *Reuters* article.

Plaintiffs also fail to establish strong circumstantial evidence that Defendants knew that their statements regarding growth in Japan were false or misleading when made, or recklessly disregarded that possibility. Plaintiffs' entire argument regarding scienter for these statements hinges on Defendants' revelation on April 19, 2018 that growth in Japan was slower than expected. Yet as described above, Plaintiffs' argument that Defendants should not have represented inflated market share numbers or projections at CAGNY merely amounts to a claim of "fraud by hindsight."

Finally, Plaintiffs allege that Defendants Calantzopoulos, Olczak, King, Picavet, and Peitsch had access to non-public information about the Company by virtue of their positions within the Company. CAC ¶ 311. They further allege that Defendants Calantzopoulos, King,

Olczak, and Picavet were all executive officers or in top management positions at Philip Morris and, at a minimum, would have been aware of key facts related to the Company's operations. CAC ¶ 314. "It is well established," however, "that boilerplate allegations that defendants knew or should have known of fraudulent conduct based solely on their board membership or executive positions are insufficient," standing alone, "to plead scienter." *In re Sotheby's Holdings, Inc.*, No. 00-CV-1041 (DLC), 2000 WL 1234601, at *7 (S.D.N.Y. Aug. 31, 2000) (quoting *Novak*, 216 F.3d at 309). Moreover, "[t]he continued viability of the core operations theory . . . is uncertain." *In re Inv. Tech.*, 251 F. Supp. 3d at 624. "Even assuming the theory remains viable, recent case law within this Circuit indicates that reliance on a 'core operations' inference may provide 'supplemental support' for establishing scienter, but is not independently sufficient." *Id.* (citing *Celestica*, 455 F. App'x at 14 n. 13). Accordingly, even assuming the core operations theory remains viable, these boilerplate allegations are insufficient to establish scienter.

II. Section 20(a)

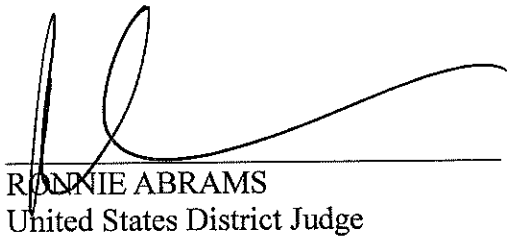
Control person liability under Section 20(a) requires an underlying primary violation of Section 10(b) of the Securities Exchange Act. *See ATSI*, 493 F.3d at 108. Since Plaintiffs have failed to adequately plead a violation of Section 10(b), their claim for Section 20(a) control person liability by the Individual Defendants also fails. *See, e.g., Das v. Rio Tinto PLC*, 332 F. Supp. 3d 786, 817-18 (S.D.N.Y 2018); *Lopez*, 173 F. Supp. 3d at 42; *In re Lululemon*, 14 F. Supp. 3d at 587.

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss the Consolidated Amended Class Action Complaint is granted. With the exception of Plaintiffs' claims with respect to the four undisclosed studies, the claims are dismissed with prejudice. If Plaintiffs intend to file a Second Amended Class Action Complaint they shall do so no later than March 3, 2020. The Clerk of Court is respectfully directed to terminate the motions pending at Dkts. 106 and 107.

SO ORDERED.

Date: February 4, 2020
New York, New York



RONNIE ABRAMS
United States District Judge