

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

THOMAS BIONDOLILLO and KEVIN  
GARDECK, individually and on behalf of  
all others similarly situated,

Plaintiff,

v.

ROCHE HOLDING AG, SEVERIN  
SCHWAN, ALAN HIPPE, DANIEL  
O'DAY, and GOTTLIEB A. KELLER,

Defendants.

Civ. No. 17-4056

**OPINION**

THOMPSON, U.S.D.J.

**INTRODUCTION**

This matter comes before the Court upon the Motion to Dismiss filed by Defendants Roche Holding AG (“Roche”), Severin Schwan, Alan Hippe, Daniel O’Day, and Gottlieb A. Keller (collectively, “Defendants”). (ECF No. 58.) Plaintiffs Thomas Biondolillo and Kevin Gardeck (collectively, “Plaintiffs”), on behalf of a putative class, oppose. (ECF No. 62.) The Court has decided the Motion on the written submissions of the parties, pursuant to Local Rule 78.1(b). For the reasons stated herein, the Motion is granted.

**BACKGROUND**

This is a securities case involving the release of “top-line” results of a pharmaceutical drug trial. Plaintiffs are investors representing a putative class; Defendants are the pharmaceutical company and four of its executives. (3d Am. Compl. (“TAC”) ¶¶ 27–33, ECF No. 56.) The Court previously dismissed the First Amended Complaint (1st Op., ECF No. 35; 1st Order, ECF No. 36) and Second Amended Complaint (2d Op., ECF No. 54; 2d Order, ECF No.

55) because they failed to show that any of Defendants' statements were false or misleading.<sup>1</sup> Plaintiffs then filed a Third Amended Complaint, adding a single allegation: Defendants' statements about the drug trial results were misleading because they failed to disclose a conflict of interest. (*See* Redlined TAC ¶¶ 11–12, 139–44, 150, ECF No. 60 (showing new material in the TAC).)

Defendant Roche sponsored the APHINITY Phase III Study (“APHINITY”) to test the effects of Herceptin, Perjeta, and chemotherapy on a subset of breast cancer patients in the adjuvant (post-surgery) setting. (TAC ¶¶ 62–63, 65, 67–69.) Positive results would augur a significant increase in Defendant Roche’s revenues and market value. (*Id.* ¶¶ 66, 72.) The full APHINITY results would not be revealed until the American Society of Clinical Oncology (“ASCO”) meeting in June 2017. (*Id.* ¶ 70.) But on March 2, 2017, Defendant Roche issued a press release announcing APHINITY’s “positive results,” claiming that it found a “statistically significant improvement in invasive disease-free survival,” and “met its primary endpoint.” (*Id.* ¶ 82.)

The Breast International Group (“BIG”) was one of the collaborators on APHINITY, and Dr. Jose Baselga was an executive member of BIG at that time. (*Id.* ¶ 69.) Dr. Baselga also served as a trial investigator in the APHINITY study and was listed as an author in the *New England Journal of Medicine* publication of the study. (*Id.* ¶¶ 68, 137.) Roche had paid Dr. Baselga over \$3 million for consulting fees and for his stake in a company that Roche acquired. (*Id.* ¶¶ 11, 22, 137.) The March 2, 2017 press release did not disclose these payments. (*Id.* ¶¶ 11.) After the full APHINITY results were released at the ASCO meeting on June 5, 2017, “the consensus by [o]ncologists [was] that the study was a disappointment, [but Dr.] Baselga [told]

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<sup>1</sup> The First Amended Complaint was dismissed in part for the additional reason that it failed to plead scienter for all Defendants. (1st Op. at 11–12.)

analysts that the critiques were ‘weird’ and ‘strange.’” (*Id.* ¶ 129.)

On September 8, 2018, the *New York Times* published an article revealing that Dr. Baselga had received over \$3 million in payments from Roche. (*Id.* ¶¶ 22, 137.) The article went on to say that Dr. Baselga “put a positive spin on the results of two Roche-sponsored clinical trials that many others considered disappointments, without disclosing his relationship to the company.” (*Id.* ¶ 136.) After the *New York Times* article was published, Dr. Baselga resigned from his positions at Memorial Sloan Kettering Cancer Center and the medical journal *Cancer Discovery*. (*Id.* ¶¶ 138, 140.) ASCO forced Dr. Baselga to correct his disclosures, and the *New England Journal of Medicine* published a correction to its publication of the APHINITY results to disclose Roche’s payments to Dr. Baselga. (*Id.* ¶ 142.)

Plaintiffs filed the Third Amended Complaint on April 24, 2019, alleging violations of Section 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5 (TAC ¶¶ 171–80); Section 20(a) of the Securities Exchange Act, 15 U.S.C. § 78t(a) (TAC ¶¶ 181–86); and Section 20A of the Securities Exchange Act, 15 U.S.C. § 78t-1 (TAC ¶¶ 187–95). Defendants moved to dismiss on May 8, 2019. (ECF No. 58.) After receiving an automatic extension of time under Local Civil Rule 7.1(d)(5) (*see* Request, ECF No. 61), Plaintiffs opposed the Motion on June 3, 2019 (ECF No. 62). Defendants replied on June 10, 2019. (ECF No. 63.) The Motion is presently before the Court.

### **LEGAL STANDARD**

A motion to dismiss under Rule 12(b)(6) of the Federal Rule of Civil Procedure tests the sufficiency of a complaint. *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). The defendant bears the burden of showing that no claim has been presented. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). When considering a Rule 12(b)(6) motion, a district court should

conduct a three-part analysis. *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). “First, the court must ‘take note of the elements a plaintiff must plead to state a claim.’” *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)). Second, the court must “review[] the complaint to strike conclusory allegations.” *Id.*; *see also Iqbal*, 556 U.S. at 679. Finally, the court must assume the veracity of all well-pleaded factual allegations and “determine whether the facts are sufficient to show that plaintiff has a ‘plausible claim for relief.’” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (quoting *Iqbal*, 556 U.S. at 679); *see also Malleus*, 641 F.3d at 563. If the complaint does not demonstrate more than a “mere possibility of misconduct,” it must be dismissed. *See Gelman v. State Farm Mut. Auto. Ins. Co.*, 583 F.3d 187, 190 (3d Cir. 2009) (quoting *Iqbal*, 556 U.S. at 679).

Additionally, in a securities case, the Private Securities Litigation Reform Act (“PSLRA”) imposes a more demanding pleading standard. To allege a false or misleading statement or omission, the complaint must “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.” 15 U.S.C. § 78u-4(b)(1). This pleading standard is effectively the same as the one provided by Rule 9(b) of the Federal Rules of Civil Procedure, which requires that the complaint “state with particularity the circumstances constituting fraud.” *Inst. Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009).

Although a district court generally must confine its review on a Rule 12(b)(6) motion to the pleadings, *see Fed. R. Civ. P. 12(d)*, “a court may consider certain narrowly defined types of material” beyond the pleadings, *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999), including matters incorporated by reference or integral to the claim, items subject

to judicial notice, matters of public record, orders, and items appearing in the record of the case. *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (internal citation omitted).

### **DISCUSSION**

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must show “(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.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (citing *Stoneridge Inv. Partners, LLC v. ScientificAtlanta, Inc.*, 552 U.S. 148, 157 (2008)); accord *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014). This case raises the interesting question of whether publishing the results of a study without disclosing conflicts of interests is a misrepresentation. But however that question might be answered in the abstract, any alleged misrepresentation by Defendants in this matter was not material and did not cause Plaintiffs any loss.

As for materiality, “[i]n . . . an efficient market, ‘information important to reasonable investors . . . is immediately incorporated into the stock price.’” *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1425 (3d Cir. 1997)). As a result, if a company discloses information that it had previously withheld, and the company’s stock price does not change upon disclosure, then the information disclosed is not material. *Id.* (citing *Burlington*, 114, F.3d at 1425); *In re Merck & Co. Sec. Litig.*, 432 F.3d 261, 269 (3d Cir. 2005).

As for loss causation, “[w]here the value of the security does not actually decline as a result of an alleged misrepresentation, it cannot be said that there is in fact an economic loss attributable to that misrepresentation.” *Semerenko v. Cedant Corp.*, 223 F.3d 165, 185 (3d Cir.

2000). To prove loss causation, a plaintiff must show that the misrepresentation was the proximate cause of the decline in the security's value. *Id.*

Plaintiffs claim that the March 2, 2017 press release was a misrepresentation because it failed to disclose Dr. Baselga's conflict of interest. To demonstrate that this alleged misrepresentation both was material and caused loss, Plaintiffs must show that Defendant Roche's stock price fell when Dr. Baselga's conflict was finally revealed to the public.

Defendant Roche's stock price declined significantly when the full APHINITY results were released at the ASCO meeting on June 5, 2017; however, Dr. Baselga's conflict of interest was not revealed at that time, so logically disclosure of the conflict of interest could not have caused the decline in stock price. (*See* TAC ¶ 135 ("It was not until after the close of the Class Period [on June 5, 2017] that Dr. Baselga's positive statements touting the Study results at the June 2017 ASCO conference made sense. He had been bought and paid for by Roche."))

*Share price and volume graph for Roche (Roche ADR (RHHBY)) - 23/02/2017 - 12/06/2017*



Roche, *Share Information*, <https://www.roche.com/investors/shares.htm> [<http://perma.cc/C4R5-X3KT>] (last visited June 12, 2019) (hereinafter, "*Share Information*").

The article in the *New York Times*, published on September 8, 2018, revealed Dr.

Baselga’s conflicts of interest (TAC ¶¶ 22, 137), and on October 18, 2018, the *New England Journal of Medicine* corrected its publication to disclose Dr. Baselga’s conflicts (*id.* ¶ 142). But Defendant Roche’s stock price barely moved—and even increased—after these revelations.<sup>2</sup>

*Share price and volume graph for Roche (Roche ADR (RHHBY)) - 31/08/2018 - 25/10/2018*



*Share Information; accord Roche Holding Ltd ADR Historical Stock Prices, ECF No. 58-11.*

Because Defendant Roche’s stock price did not decline significantly after either event that could qualify as a disclosure, Plaintiff has failed to plead materiality and loss causation and therefore fails to state a claim under Section 10(b).<sup>3</sup>

**CONCLUSION**

For the foregoing reasons, Defendants’ Motion to Dismiss is granted. An appropriate order will follow.

Date: 6/17/19

/s/ Anne E. Thompson  
ANNE E. THOMPSON, U.S.D.J.

<sup>2</sup> Although the stock price eventually fell a few days after the *New England Journal of Medicine* correction was issued, materiality is determined by “the period immediately following disclosure.” *In re Merck*, 432 F.3d at 269 (quoting *Oran*, 226 F.3d at 282).

<sup>3</sup> Because the Third Amended Complaint fails to state a claim under Section 10(b), it also fails to state a claim under Sections 20(a) and 20A. *See Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013) (quoting *Avaya*, 564 F.3d at 252 (3d Cir. 2009)); *Pfizer*, 754 F.3d at 175 (citing *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 541 (3d Cir. 1999)).