UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FADI DAHHAN, Individually and on Behalf of All Others Similarly Situated,	*	
Plaintiff,	*	
v.	*	Civil Action No. 1:17-cv-10511-IT
OVASCIENCE, INC., et al,	*	
Defendant.	*	

MEMORANDUM & ORDER

July 31, 2018

TALWANI, D.J.

Lead Plaintiff Freedman Family Investments LLC ("Freedman Family") brings this action against Defendants OvaScience, Inc. ("OvaScience"), Michelle Dipp, and Jeffrey Young. Count I of the Amended Class Action Complaint [#27] alleges that OvaScience and Dipp artificially raised the market price of OvaScience's stock by disseminating false and misleading information and failing to disclose material facts, in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder. Count II alleges that Dipp and Young are liable under Section 20(a) of the Exchange Act, because they were controlling persons of OvaScience and thus had the ability to prevent issuance of false statements. Defendants move to dismiss the claims against them for failure to state a claim on which relief may be granted, pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, Defendants' motion is DENIED.

I. Background[1]

OvaScience is a fertility company launched in 2011. Compl. ¶ 2 [#27]. It has developed to the point of commercialization only one potential treatment. Id. That treatment, known as AUGMENT, involves "harvesting mitochondria from [a woman's immature egg cells (also called "egg precursor cells" or "EggPC cells")] and injecting them into her egg at the time of [in vitro fertilization ("IVF")] in order to supplement the energy level in the egg and to address problems caused in the development of newly formed embryos by inadequate energy in the cell division process." Id.

OvaScience first sought to launch AUGMENT in the United States. Id. ¶ 3. When it began its U.S.-based study in February 2013, OvaScience stated that it would commercialize the treatment only if it showed "positive efficacy and safety." Id. ¶¶ 3, 35-36.

OvaScience subsequently received a letter from the Food and Drug Administration ("FDA") advising OvaScience to file an investigational new drug application for AUGMENT. Id. ¶ 37. "Instead of facing that [review and approval process] and pursuing clinical data evidencing AUGMENT's efficacy," OvaScience "discontinued its U.S.-based clinical study and transferred its study overseas." Id. ¶ 38. It developed a plan that involved partnering with IVF clinics in other international regions, first providing free treatment cycles, and then turning them into commercial centers for the treatment. Id. ¶ 39. In January 2014, OvaScience stated that it would introduce these programs "for physicians to gain experience using AUGMENT and to generate data." Id. ¶ 39. OvaScience announced a plan to initiate 40 to 60 AUGMENT cycles in

[1] For purposes of resolving the Rule 12(b)(6) motion, the court accepts the factual allegations in the Amended Class Action Complaint ("Complaint") [#27] as true. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007).

2014, that these initial cycles would be free, but with the goal of ultimately charging for AUGMENT by the end of 2014. Id. ¶ 41.

At its first Investor Day on December 17, 2014, Defendants announced that AUGMENT had performed 150 cycles by the end of 2014, and had "transitioned some of its IVF clinics to commercial centers." Id. ¶ 14. Treatment added $15,000 to $25,000 to the cost of each IVF cycle, and involved an invasive procedure, id. ¶ 58, but Defendants nonetheless stated that they expected 1,000 paying patients in 2015. Id. ¶¶ 45-47. In response to this news, OvaScience stock increased from a closing price of $29.38 on December 16, 2014, to $47.85 on December 19, 2014, a 62.87% increase in value. Id. ¶ 48.

OvaScience completed a secondary public offering of the company's stock on January 13, 2015. Id. ¶¶ 6, 77. Through the offering, OvaScience sold 2,645,000 shares of common stock at $50.00 per share, raising $132.25 million. Id. ¶ 77.

On March 17, 2015, Defendants released abstracts containing the first AUGMENT clinical data. Id. ¶ 50. The fact that Defendants had released some data was encouraging to investors, who had not expected metrics at that time. Id. ¶ 51. OvaScience's stock price on March 25, 2015, closed at $49.80. Id. ¶ 53.

Defendants then issued two additional press releases on March 26 and March 28, and held a public conference call on March 27 regarding the actual data. Id. ¶¶ 50, 117. The results revealed data for only 34 patients from two clinics, even though OvaScience had offered free AUGMENT cycles to 150 patients at that point. Id. ¶ 51. While Defendants highlighted a purported pregnancy success rate of 53% for the Canadian patients, that rate was based on a subset of women who had developed viable embryos for transfers, and did not include those who did not develop any viable embryos. Id. ¶ 52. The real pregnancy success rate was approximately

27% of the Canadian patients, and 23.5% for all 34 patients (including the non-Canadian patients). Id. ¶¶ 52, 117. By contrast, the success rate of IVF without AUGMENT for a similar patient population is 33%. Id. ¶¶ 55-56. OvaScience's stock price dropped to $38.18 by March 30, 2015. Id. ¶ 120.

Through August, Defendants continued to reassure the market that OvaScience was on track to sell 1,000 cycles in 2015. Id. ¶¶ 58-59. But between January and August, 2015, Defendants sold, at most, 17 AUGMENT cycles. Id. ¶ 66.

On September 29, 2015, Defendants revealed that OvaScience had only had approximately 35 commercial patients in 2015, and that the majority of those treatments occurred in September 2015. Id. ¶¶ 62, 66. OvaScience's stock price dropped by 40.98% on the day of the announcement, and fell further the following trading day. Id. ¶ 63.

II. Discussion

A. Standard

When considering a motion to dismiss for failure to state a claim made pursuant to Fed. R. Civ. P. 12(b)(6), the court must "examine whether the operative complaint states a claim for which relief can be granted, construing the well-pleaded facts in the light most favorable to the [claimant], accepting their truth and drawing all reasonable inferences in [claimant's] favor." Ruivo v. Wells Fargo Bank, N.A., 766 F.3d 87, 90 (1st Cir. 2014).

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

A plaintiff alleging securities fraud must allege "(1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." In re Boston Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012) (quoting Miss. Pub. Empls.' Ret. Sys. v. Boston Sci. Corp., 523 F.3d 75, 85 (1st Cir.

2008)). Defendants contend that Count I fails because the Complaint does not plead facts to sufficiently allege scienter; the statements at issue were not false or misleading, and the allegedly false statements are forward-looking statements that are inactionable under the safe harbor of the Private Securities Litigation Reform Act ("PSLRA"). Defendants also contend that the Complaint does not state a claim for Defendants' failure to disclose information about risks under Item 303 or Item 503 of Regulation S-K, 17 C.F.R. § 229.303, because the Complaint does not allege what risk factor Defendants failed to disclose. These arguments are addressed below, though not in the same order.

i. Truthfulness of the statements.

To plead falsity under the PSLRA, a plaintiff must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." Hill v. Gozani, 638 F.3d 40, 55 (1st Cir. 2011) (alternation in original) (quoting 15 U.S.C. § 78u-4(b)(1)). The Complaint alleges on numerous specified occasions between December 2014 and August 2015, OvaScience and Dipp made false or misleading representations that there was a demand for the AUGMENT treatment and that the Company expected to have, or was on track to have, at least 1,000 AUGMENT patients by the end of 2015.[2] Defendants contends that these statements were never false nor misleading. Def. Mem. 14-18 [#31]. This argument fails.

[2] See Compl. ¶ 84 [#27] (on December 17, 2014, OvaScience filed a Form 8-K stating, "In 2015, the Company expects at least 1,000 additional patients to be receiving the AUGMENT treatment"); id. ¶ 85 (on December 17, 2014, Dipp stated that the Company's experience with AUGMENT to date and initiation of 150 free treatments was the basis for the plan to have "at least 1,000 patients in treatment" in 2015); id. ¶ 87 (on December 17, 2014, Dipp stated that "[t]he doctors are already using AUGMENT, and we believe that, as you saw with some of the case studies. So, it's not a question of does AUGMENT work. It's a question of in which population does AUGMENT work best"); id. ¶ 88 (on December 17, 2014, Dipp explained that OvaScience had performed more free trials than expected in 2014 because of "both" the demand for treatment and the success of the treatment); id. ¶¶ 94, 96 (Company stated, "In 2015, we expect at least 1,000 additional patients to be receiving the AUGMENT treatment" in both

Defendants emphasize that OvaScience exceeded the number of free treatment cycles it had expected to initiate in 2014 by a significant margin, performing over 150 cycles rather than the anticipated 40-60 cycles. But while the number of free treatment cycles performed in 2014 may have factored into OvaScience's setting of an initial goal of 1,000 paid treatments, the 2014 experience with free treatments is of no moment in assessing whether OvaScience's 2015 statements regarding enrollment for paid treatment cycles was misleading.

Defendants argue next that Plaintiff has not identified a specific point in time when the statements became factually misleading, and instead resorts to "gross generalizations" as to when Defendants knew that OvaScience would not reach its goal. In Defendants' view, the claim is not sufficiently specific because "the first moment in time Plaintiff identifies when the Company knew concretely that it would not reach its goal[] is the moment in September 2015, when

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January 6, 2015 Preliminary Prospectus Supplement and January 7, 2015 Prospectus Supplement); id. ¶ 98 (at JPMorgan Health Conference on January 14, 2015, Dipp emphasized the success of AUGMENT in 2014 and stated that OvaScience "will treat 1,000 patients" in 2015); id. ¶ 100 (in March 16, 2015 news release and March 16, 2015 Form 8-K filing, Dipp stated that Company "anticipates expanding the availability of the AUGMENT treatment and expects 1,000 AUGMENT treatment cycles will be in process by the end of 2015"); id. ¶ 101 (in March 16, 2015, Annual Report for fiscal year 2014, which was filed with the SEC that same day on Form 10-K, stated, "We expect 1,000 AUGMENT treatment cycles will be in process by the end of 2015"); id. ¶ 105 (May 11, 2015 news release filed with the SEC on Form 8-K stated, "We are confident in our ability to achieve our goals this year as demand for the AUGMENT treatment grows," OvaScience was "On Track to Meet 2015 AUGMENT Cycles Goal," and OvaScience "anticipates meeting the Company's own limit of 1,000 AUGMENT treatment cycles in process by the end of the year"); id. ¶106 (May 11, 2015, Quarterly Report, filed on Form 10-Q, stated, "We expect 1,000 AUGMENT treatment cycles will be in process by the end of 2015"); id. ¶ 109-10 (August 10, 2015, press release stated, "The Company continues to expect to reach its goal of 1,000 AUGMENT treatment cycles in progress by the end of 2015," and that "major IVF clinic networks all over the world have approached us about offering the treatment to their patients"); id. ¶ 111 (August 10, 2015, Quarterly Report, filed with the SEC on Form 10-Q, stated, "We continue to expect to achieve our goal of 1,000 AUGMENT treatment cycles in 2015"); id. ¶ 113 (on August 11, 2015, Dipp declined "to say the number of biopsies that we've achieved this quarter" but stated, "We do continue to expect to achieve our goal of 1,000 AUGMENT treatment cycles in process").

Defendants disclosed that they had initiated approximately 35 cycles, the majority of which had occurred that month." Def. Mem. 15 (emphasis in original) [#31].[3] But the issue is not when Defendants first realized that they were not on track to hit the 1,000-cycle target, but whether they had that knowledge at the time when they made the statements that they were on track. And Plaintiff's allegations, if credited, provide sufficient facts from which a jury could infer that Defendants had that knowledge at the time of the statements, where the free 2014 treatment cycles could not be reliable indicators of demand for a $15,000 to $20,000 procedure, where Defendants had no meaningful information supporting a claim of efficacy (and indeed, as of March 2015, had data suggesting that the procedure was counter-productive), and where Defendants' representations that they were "on track" can reasonably be understood as implying that Defendants were aware at least of the approximate number of how many (or how few) individuals had agreed to pay for these procedures at the time the statements were being made.

Defendants assert further that the statements were not false and misleading because they were consistent with the OvaScience's publicly-disseminated revenue projections which explained that there would be a delay in recognizing revenue for 30 to 120 days from the start of treatment, and that OvaScience did not expect significant AUGMENT revenue until the second half of 2015, with a majority of revenue recorded in the fourth quarter. But the delayed revenue projections make the statements worse, not better for Defendants, for with a 30- to 120-day delay for revenue, in order to have a majority of revenue record in the fourth quarter of 2015, a

[3] Defendants assert further that "Plaintiff admits . . . that the Company all along 'had anticipated the majority of AUGMENT treatment cycles would initiate in the fourth quarter [of 2015].'" Def.'s Mem. 15 [#31] (purportedly quoting paragraph 131 of the Complaint, with emphasis added by Defendants' counsel). A proper citation would have made clear that this sentence, as formatted in the Amended Complaint, was a quotation of a statement allegedly made by Defendant Dipp. The argument that Dipp's reported statement is somehow Plaintiff's admission is baffling.

majority of the treatment cycles would have had to be started in the third quarter of 2015. Instead, only 3.5% of the treatment cycles had been started at that point.

Defendants next challenge two particular statements by Dipp on December 17, 2014, alleged in the Complaint to be false and misleading. First, Dipp stated that "[t]he doctors are already using AUGMENT, and we believe that, as you saw with some of the case studies. So, it's not a question of does AUGMENT work. It's a question of in which population does AUGMENT work best." Compl. ¶ 87. Second, Dipp explained that OvaScience had performed more free trials than expected in 2014 because of "both" the demand for treatment and the success of the treatment. Id. ¶ 88. Defendants argue that these statements as to the success and demand for AUGMENT are not actionable because "OvaScience had consistently disclosed to the market the significant and ongoing losses it had incurred and expected to incur in the future, in light of which no reasonable investor could have been misled concerning the Company's prospects." Def. Mem. 17 [#31]. But disclosures as to losses occurred in the early stages of product research and as to development and funding capital that still needed to be raised would only be part of the information an investor would reasonably consider material in evaluating the treatment's potential commercial success, and in no way negates the materiality of Dipp's statements suggesting that the AUGMENT treatment was effective.

ii. *Defendants' additiona*l arguments as to why the statements are not actionable

Defendants argue further that each allegedly false statement the Complaint identifies was accompanied by cautionary statements and is therefore inactionable under the PSLRA safe harbor. Def. Mem. 19 [#31]. The PSLRA provides a safe harbor provision for, as relevant here, forward-looking statements that are identified as forward-looking statements and are accompanied by meaningful cautionary statements identifying important factors that could cause

actual results to differ materially from those in the forward-looking statement. 15 U.S.C. § 78u–5(c)(1). Plaintiff and Defendants disagree as to whether the cautionary statements, which are provided in exhibits to Defendants' Memorandum in Support of Motion to Dismiss [#31], were sufficient as to forward-looking statements. Regardless of the merits of this dispute, however, at least some of the allegedly false statements were not forward-looking. The Complaint, for example, alleges that Dipp made two statements on December 17, 2014, suggesting that the AUGMENT treatment was effective. See Compl. ¶¶ 87-88. Those statements did not have a forward-looking element. Moreover, the Complaint alleges that OvaScience made a number of false or misleading statements that it was on track to achieve 1,000 treatment cycles in 2015. See, e.g., Compl. ¶¶ 84, 94, 96, 100-01, 105-06, 110-13. Though the estimate that OvaScience would achieve 1,000 cycles is forward-looking, the element of Defendants' statements that pertained to the status of Defendants' current expectations or status were not forward-looking, and are not protected by the safe harbor. See N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 45 n.13 (1st Cir. 2008) ("In analyzing a forward-looking statement, the aspect of the statement that is based on the present fact must be distinguished from the aspect of the statement that is a future projection. 'The safe harbor . . . is intended to apply only to allegations of falsehood as to the forward-looking aspects of the statement.'" (quoting In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 213 (1st Cir. 2005)). And, in addition to the allegations regarding false or misleading statements, Plaintiff also alleges that Defendants are liable for misleading omissions, including the omission of treatment results and sales numbers. See, e.g., Compl. ¶¶ 5-10, 45, 51, 72-74. Omissions of existing facts are not forward-looking statements, and are not protected by the PSLRA safe harbor.

Next, Defendants contend that the Complaint does not state a claim premised on Defendants' failure to make certain mandatory disclosures under Items 303 and 503.[4] Def. Mem. 19-20 [#31]. To state a claim under Items 303 and 503, a plaintiff must allege that the registrant knew at the time of an offering that a risk factor or uncertainty existed. See Silverstrand Invs. v. AMAG Pharms., Inc., 707 F.3d 95, 103 (1st Cir. 2013). Because the Complaint alleges sufficient facts to infer that, at the time of the January 2015 offering, Defendants knew that Dipps' statements regarding the efficacy of AUGMENT were misleading, the Complaint sufficiently states a claim based on Defendants' failure to make mandatory disclosures.

iii. Scienter

To prove scienter, a plaintiff must show "that defendants either 'consciously intended to defraud, or that they acted with a high degree of recklessness.'" Miss. Pub. Emps.' Ret. Sys., 523 F.3d at 85 (quoting Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002)). Recklessness consists of "a highly unreasonable omission, involving not merely simple, or even inexcusable, negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it." City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011). The scienter inquiry is whether "all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual

[4] Under Item 303 of Regulation S-K, 17 C.F.R. § 229.303(a), a company has an affirmative duty to disclose "any known trends or any known demands, commitments, events or uncertainties that will result in or that are reasonably likely to result in the registrant's liquidity increasing or decreasing in any material way," as well as "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. §§ 229.303(a)(1) and (a)(3)(ii). Item 505 of Regulation S-K requires a disclosure of "the most significant factors that make the offering speculative or risky." Id. § 229.503(c).

allegation, scrutinized in isolation, meets that standard." Tellabs, 551 U.S. at 322-23. A plaintiff must not only "allege facts from which an inference of scienter rationally could be drawn," but must "plead with particularity facts that give rise to a 'strong'—i.e., a powerful or cogent—inference." Id. at 323. "When there are equally strong inferences for and against scienter, the draw is awarded to the plaintiff." City of Dearborn Heights Act 345 Police & Fire Ret. Sys., 632 F.3d at 757.

Defendants argue that Plaintiff is improperly trying to establish scienter based on Dipp's position within the company, rather than on her actual knowledge. But the Complaint's allegations, read collectively and in the light most favorable to Plaintiff, are sufficient to establish a strong inference of scienter for several reasons. First, the successful commercialization of AUGMENT was critical for OvaScience's success, as it was the company's only developed treatment. Compl. ¶ 2. Moreover, OvaScience's ability to develop additional treatments derived from the controversial EggPC science underlying AUGMENT was dependent on achieving successful scientific and commercial results. See id. ¶¶ 32, 35. The importance of AUGMENT supports the inference that Defendants knew of the Company's sales and inability to sell 1,000 cycles.

Defendants argue that even where statements concern "core operations," Defendants must have had access to data contradicting those statements before they become actionable. Def.'s Mem. 11-12 [#31] (citing GBR Grp., Ltd. v. Biogen Inc. (In re Biogen Inc. Sec. Litig.), 857 F.3d 34, 44 (1st Cir. 2017)). Here, however, the Complaint alleges that the stated purpose of the clinic trial was to gather data about AUGMENT's efficacy as a predicate to commercialization, see Compl. ¶ 36, and that Defendants themselves claimed to maintain a presence at every IVF clinic performing AUGMENT, to conduct part of every AUGMENT

cycle, to have created a registry of AUGMENT data, and to closely track all aspects of the treatment.[5] These allegations, if true, support the strong inference Defendants knew, or were recklessly unaware of, the data about AUGMENT's efficacy when they began commercializing AUGMENT in December 2014 and represented that the data confirmed AUGMENT's efficacy.

Additionally, the Complaint alleges that during clinical trials in 2014, Defendants provided quarterly updates on the number of cycles performed. Id. ¶¶ 42, 44. After Defendants started selling AUGMENT, however, they ceased providing quarterly metrics, explaining, "[W]e are not going to say the number of [cycles] that we've achieved this quarter," but "[w]e do continue to expect to achieve our goal of 1,000 AUGMENT treatment cycles in process." Id. ¶ 72. Drawing the inference most favorable to Plaintiff, Defendants may have changed their reporting practices in order to conceal poor sales figures and bolster the claim that the Company expected to achieve 1,000 cycles.

Finally, Defendants argue that statements of confidence that OvaScience would achieve 1,000 cycles in 2015 were not false or misleading because they were correct when made. The reason that the Company ultimately failed to reach that goal, Defendants argue, was because "M&A [mergers and acquisitions] activities" caused a short-term delay. Def.'s Mem. 15 [#31]. The inability to sell AUGMENT cycles, however, proved to be permanent. Id. ¶ 141. Drawing inferences in the light most favorable to the Plaintiff suggests that Defendants' explanation was a

[5] Specifically, the Complaint alleges that OvaScience maintained labs within or next to each IVF trial clinic; that OvaScience employees administered free AUGMENT treatments, trained the clinics' physicians on the treatment, and were stationed at the clinics to report the number of AUGMENT treatments in real time; that Dipp and other OvaScience executives regularly visited clinics and had access to data on AUGMENT treatments; and that Dipp routinely discussed AUGMENT data, stating that the information was known through sources including patient case studies, the international data registry, and on-site clinical visits. Compl. ¶¶ 40, 70-71 [#27].

false excuse. And, because a company exercising reasonable diligence should have investigated why it failed to achieve its publicly-stated goal, to the extent that the explanation offered was untrue, one can infer that Defendants either knowingly misrepresented the reason or recklessly failed to investigate the reason. Defendants argument to the contrary that the Complaint fails to allege scienter because it does not allege "common indicia of scienter" such as "any confidential witness with relevant knowledge whose direct observations might support a strong inference of scienter," or "unusual or unlawful training," Def. Mem. 12 [#31], is unavailing, as no particular types of indicia of scienter are required. The particularized allegations in the Complaint, taken collectively, if true, give rise to an inference of scienter that is "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324.

C. Count II: Section 20(a) of the Exchange Act

Section 20(a) of the Exchange Act imposes liability on "[e]very person who, directly or indirectly, controls any person liable" for a securities fraud violation. 15 U.S.C. § 78t(a). Section 20(a) therefore "only creates liability derivative of an underlying securities violation." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 67 (1st Cir. 2008). Defendants contend that Plaintiff's Section 20(a) claim fails because the Complaint fails to state a claim for an underlying securities violation. Def. Mem. 20 [#31]. Because the court disagrees with this premise, for the reasons set forth above, the court finds too that the Complaint has sufficiently stated a Section 20(a) claim.

III. Conclusion

For the reasons set forth above, Defendants' Motion to Dismiss the Amended Class Action Complaint [#30] is DENIED.

IT IS SO ORDERED.

Date: July 31, 2018

/s/ Indira Talwani
United States District Judge