UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: OCULAR THERAPEUTIX, INC. SECURITIES LITIGATION	)	Civil Action No. 17-12288-GAO <u>CONSOLIDATED</u>
THOMAS GALLAGHER, individually and on behalf of all others similarly situated, Plaintiff, v. OCULAR THERAPEUTIX, INC., et al., Defendants.	)	Civil Action No. 17-12288-GAO
DYLAN CARAKER, individually and on behalf of all others similarly situated, Plaintiff, v. OCULAR THERAPEUTIX, INC., et al., Defendants.	)	Civil Action No. 17-12146-GAO
SHAWNA Kim, individually and on behalf of all others similarly situated, Plaintiff, v. OCULAR THERAPEUTIX, INC., et al., Defendants.	)	Civil Action No. 17-12286-GAO

OPINION AND ORDER
April 30, 2019

O'TOOLE, D.J.

Lead plaintiffs[1] bring this securities fraud action against Ocular Therapeutix, Inc. and executives Amarpreet Sawhney and Eric Ankerud (the "Individual Defendants"), for themselves and on behalf of all other investors who purchased or otherwise acquired Ocular securities between March 10, 2016, and July 11, 2017.[2] The two-count Consolidated Amended Class Action Complaint alleges violations of (1) Section 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission ("SEC") Rule 10b-5 against all defendants, and (2) Section 20(a) of the Exchange Act against the Individual Defendants. Before the Court is the defendants' motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), the Exchange Act, and the Private Securities Litigation Reform Act ("PSLRA").

I. Background

A. Ocular's Business and September 2015 New Drug Application

Ocular is a Massachusetts-based biopharmaceutical company that focuses on the development and commercialization of therapies for diseases and conditions of the eye. In September 2015, Ocular submitted a New Drug Application ("NDA") to the Food and Drug Administration seeking approval to market its drug candidate Dextenza for the treatment of post-

[1] In March 2018, the Court appointed the group consisting of William L. Stephens, Kavita Mehta, and Oleg Tkalych (collectively, the "Ocular Investor Group"), and Khaled Ramadan as lead plaintiffs and consolidated Gallagher v. Ocular Therapeutix, Inc., No. 17-cv-12288-GAO, Caraker v. Ocular Therapeutix, Inc., No. 17-cv-12146-GAO, and Kim v. Ocular Therapeutix, Inc., 17-cv-12286-GAO, into In re Ocular Therapeutix, Inc. Securities Litigation, 17-cv-12288-GAO. (Order Consolidating Related Actions 2–4 (dkt. no. 62).)

[2] The plaintiffs also brought suit against Andrew Hurley and George V. Migausky, but now concede the claims against them should be dismissed. (Pls.' Mem. of Law in Opp'n ("Pls.' Opp'n") 1 n.2 (dkt. no. 69).)

surgical ocular pain and inflammation in human patients. Dextenza is a medical implant (a "plug") designed to be inserted into the canaliculi (ducts) of the eyes (*i.e.*, an "intracanalicular insert"). After insertion, the product releases its active pharmaceutical ingredient in Ocular's proprietary "hydrogel" onto the surface of the eye. The hydrogel is designed to provide sustained delivery of its active ingredient to the eye and to act as an ocular tissue sealant.

The FDA accepted Ocular's NDA for filing and established July 24, 2016 as a target date for action on the application under the Prescription Drug User Fee Act ("PDUFA"). In February 2016, as part of its ongoing review of Ocular's NDA for Dextenza, the FDA conducted a pre-approval inspection of the Company's manufacturing operations in Bedford, Massachusetts. Thereafter, the inspector issued a "Form 483" letter to the Company on February 11, 2016 ("February 2016 Form 483"), identifying "observations" from the inspection process related to record keeping, non-representative samples, control procedures, timing, laboratory controls, personnel, and building conditions, among other matters. (Consolidated Am. Class Action Compl. ("Compl.") ¶¶ 33–39 (dkt. no. 63); Decl. of Peter J. Kolovos ("Second Kolovos Decl."), Ex. A at 2–9, Oct. 4, 2018 (dkt. no. 71-1).)

On March 10, 2016, Ocular filed with the SEC its Annual Report on Form 10-K for the year 2015 (the "2016 Form 10-K"). Although Ocular had received the February 2016 Form 483 containing concerning inspectional observations, Ocular stated on the 2016 Form 10-K: "We fabricate devices and drug depot products for use in our clinical trials, research and development and commercial efforts for all of our therapeutic product candidates using current good manufacturing practices, or cGMP, at our multiproduct facility located in Bedford, Massachusetts." (Compl. ¶ 42; Decl. of Peter J. Kolovos ("Kolovos Decl."), Ex. A at 54, July 6, 2018 (dkt. no. 68-1).) It also disclosed its receipt of the February 2016 Form 483 in a way the

plaintiffs contend downplayed the extent and significance of the inspectional observations that Ocular had received:

> [I]n February 2016, as part of the ongoing review of our NDA for DEXTENZA, the FDA conducted a pre-NDA approval inspection of our manufacturing operations. As a result of this inspection, we received an FDA Form 483 containing inspectional observations focused on process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes. We addressed some observations before the inspection was closed and have responded to the FDA with a corrective action plan to complete the inspection process. . . . Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of [our product] and our product candidates that we manufacture. The failure to resolve the Form 483 inspectional observations from the February 2016 inspection could result in a delay in the PDUFA date and potential approval for the NDA we have filed for DEXTENZA for the treatment of post-surgical ocular pain.

(Compl. ¶ 43; Kolovos Decl., Ex. A at 93.)

In July 2016, Ocular received a Complete Rejection Letter ("2016 CRL") from the FDA rejecting Ocular's Dextenza NDA in its then-present form. The Company did not make the 2016 CRL itself public, but on July 25, 2016, it issued a press release regarding its receipt, stating that "[t]he concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility." (Compl. ¶ 45; Kolovos Decl., Ex. B at 2 (dkt. no. 68-2).)

That same day, Ocular's share price fell $.75, or 14.51%, to close at $4.42.

On November 9, 2016, the Company held an earnings conference call with investors, during which defendant Sawhney, Ocular's Chief Executive Officer, Chairman, and President, stated in part:

> I am pleased to report that we have had productive discussions with the FDA over the past several months. *We believe we have taken the appropriate steps to address the manufacturing related items raised by the FDA*, although the FDA will make its determination after we resubmit our NDA. As a reminder, in July we received a CRL, or complete response letter, relating to certain manufacturing processes on

> control deficiencies, and subsequently received a letter from the New England district office providing additional details as to the outstanding deficiencies related to their pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility.
>
> Among these was an observation related to the proposed process for identifying identity testing of an incoming inert gas component used in the DEXTENZA manufacturing process. The district office letter also requested that we submit a formal report providing evidence that migration to automatic integration of analytical testing has been completed.

(Compl. ¶ 69 (emphasis in original); accord Kolovos Decl., Ex. G at 3 (dkt. no. 68-7).) He also stated:

> But whether or not re-inspection is required, is a determination that [the FDA's Center for Drug Evaluation and Research] will make. And they just said that we'll get back to you in 30 days after your resubmission to inform you. That's so—we really can't get more guidance or can't give more guidance on that. *I think it's important to realize that this is a matter of when not if type of a thing, we've adequately we think addressed the issues that they've raised. And communicated our plans to them and they seem in broad agreement with the plans that we have communicated.*
>
> But until they kind of review the resubmission, they will not be in a position of giving any further guidance. So, when we do that, let's say that that were by the end of the year December we submit. In January they would let us know whether it's one more month left or five more months left.

(Compl. ¶ 71 (emphasis in original); accord Kolovos Decl., Ex. G at 10.)

B. Ocular's January 2017 NDA

On January 23, 2017, Ocular announced it had resubmitted its NDA for Dextenza.[3] On February 22, 2017, Ocular announced the FDA had accepted its NDA resubmission with a PDUFA date of July 19, 2017.

[3] A confidential witness employed by Ocular as a Regulatory Affairs Project Manager from November 1, 2016 to the end of February or early March 2017 spoke to Ankerud in "late 2016 or early 2017" before Ocular resubmitted its NDA and reports that Ankerud allegedly acknowledged that they would be including batch records in the NDA resubmission that would not meet FDA standards. (Compl. ¶ 46.)

On March 10, 2017, Ocular filed its Annual Report on Form 10-K (the "2017 Form 10-K"). The Company repeated the statement from its 2016 Form 10-K regarding cGMP, stating: "We fabricate devices and drug depot products for use in our clinical trials, research and development and commercial efforts for all of our therapeutic product candidates using current good manufacturing practices, or cGMP, at our multiproduct facility located in Bedford, Massachusetts." (Compl. ¶ 73; Kolovos Decl., Ex. H at 92 (dkt. no. 68-8).)

The FDA made additional visits to Ocular's manufacturing facilities to reinspect the facilities as part of its review of Ocular's NDA for Dextenza in April and May 2017. On May 4, 2017, the FDA issued another Form 483 letter ("May 2017 Form 483"), identifying six inspectional observations, including written records of investigations into the nature of particulate matter which had been found in the drug product, written production and process control procedures, written control unit responsibilities and procedures, laboratory controls, and training. (Compl. ¶ 50–56; Kolovos Decl., Ex. E at 2–6 (dkt. no. 68-5).)

The day after Ocular received the May 2017 Form 483, Ocular released its financial results for the first quarter of 2017 in its May 5, 2017 Quarterly Report on Form 10-Q and issued a press release that revealed that the FDA had completed inspections and that it had "received an FDA Form 483 containing inspectional observations focused on procedures for manufacturing processes and analytical testing, relating to manufacture of drug product for commercial production." (Compl. ¶ 86.)

That same day, Ocular also had a conference call for investors to discuss its disclosures and its operations. Defendant Ankerud, the Company's Executive Vice President of Regulatory, Quality, and Compliance, acknowledged the FDA's recent inspection and the Company's receipt of the May 2017 Form 483, stating:

> FDA completed the re-inspection of our facility as part of the NDA review late yesterday afternoon. As Amar mentioned, 4[8]3 was issued. We were pleased during the re-inspection that the FDA investigator was able to confirm our corrective action plan from prior observations, and indicated that there was no further follow-up necessary to close out those issues. This was a new investigator not the same investigator from prior inspections, and their primary focus in the 4[8]3 relates to a particula[te] matter issue as part of our manufacturing process. The issue relates primarily to completion of an investigation that we have underway in regard to the particular[te] matter solidifying specifications for in process, 100% visual inspection of our inserts, as well as enhancing our operator training. *We feel quite comfortable that we have the situation under control and we are preparing responses to the 4[8]3 as of this morning in anticipation of responding within 15 calendar days to the agency.* In addition to the particular matter issue, FDA raised a couple of observations in regard to analytical method, testing to be completed, as well as some other issue related to quality oversight of batch records. *So in summary, we believe that each of the observations raised by FDA during this continuous improvement review of our fully developed manufacturing process are handled well and will be resolved in our response to FDA.* We're also pleased that the collaborative nature of our NDA review has continued between the various offices of FDA, and *we're marching toward that PDUFA date and expect that we can resolve the 4[8]3 issues in a timely manner.*

(Compl. ¶ 75 (alterations and emphasis in original); accord Kolovos Decl., Ex. D at 8 (dkt. no. 68-4).)[4] He also stated:

> I think there is two important issues to recognize. The first is that from the prior preapproval inspection, FDA issued a 4[8]3. We resolve those issues, close those issues with the district office and during this re-inspection the new investigator is responsible for confirming that we have implemented what was said in our responses. And the investigator went through each of our responses and confirm that we had properly and appropriately implemented those actions. *So I think that's a strong sign that the manufacturing process has moved forward significantly, and is in a fully developed mode.*

(Compl. ¶ 77 (emphasis in original); accord Kolovos Decl., Ex. D at 13).)

On the earnings call, Ankerud rejected the notion that the May 2017 Form 483 could delay the PDUFA date. When asked by an analyst whether there was "anything in their observations that [Sawhney] [thought] could delay the action date specifically," Sawhney replied:

[4] The transcript indicates that Ankerud used the term "particular" rather than "particulate" (Kolovos Decl., Ex. D at 8). That is likely a transcription error. When quoting the transcript, both parties correct it in brackets to read "particula[te] matter."

> *Nothing that we can currently see*. I think these—as you know, probably 90% plus inspections have 483. The question is one of the nature of the issues in the 483, we think these are resolvable issues, and we have responses. Some are already prepared and some being prepared to address them in a timely fashion.

(Compl. ¶ 79 (emphasis in original); accord Kolovos Decl., Ex. D at 11.)

On May 5, 2017, following Ocular's press release, the Company's share price fell $1.47, or 16.15%, to close at $7.63.

On July 6, 2017, the website *Seeking Alpha* published an article entitled "Ocular: A Poke in the Eye." The article provided links to the February 2016 Form 483 and May 2017 Form 483, making the two forms public for the first time. The article described the content of the two forms and stated:

> Even a layperson reading this [second Form 483] can tell that the company is having serious manufacturing issues, and their whole approach to manufacturing and patient safety is highly questionable. What's more troubling is that either management doesn't fully understand the letter, or they have been misleading investors. Both are bad.

(Compl. ¶ 60.) The article also noted that observations Ocular had received in February 2016 Form 483 were repeated in the May 2017 Form 483, and that the observations in the second form were worse than the first. It noted, for instance, that one observation in the May 2017 Form 483 meant "[i]n plain English" that Ocular "still doesn't know how to make their product consistently." (Id. ¶ 61.) It noted that the Company had stated that its manufacturing "in a fully developed mode," when the "reality is, IF Dextenza is possible to manufacture on a mass scale, something which hasn't been done before, [Ocular] needs to revamp their entire process from the ground up, which can take years to do. They need to use the proper scientific tools and procedures." (Id. ¶ 62.)

That same day, another media outlet published an article about Ocular asserting that Dextenza could be rejected by the FDA because of product contamination, including aluminum, found during an FDA inspection of the manufacturing facility.

After the publication of the articles, Ocular's share price fell $3.06, or 30.06%, over the next two trading days, to close at $7.12 on July 7, 2017.

On July 12, 2017, Ocular received a second Complete Response Letter from the FDA (the "2017 CRL"), rejecting for the second time Ocular's NDA for Dextenza in its then-present form. (Id. ¶ 64.) The Company issued a press release announcing its receipt, explaining that the rejection was based on "deficiencies in manufacturing processes and analytical testing relating to manufacture of drug product for commercial production identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility that was completed in May 2017." (Id. ¶ 90.)

That same day, Ocular's share price fell $.93, or 12.24%, to close at $6.67.[5]

On December 15, 2017, the Company received a subpoena from the SEC indicating that the SEC was investigating the Company for its practices relating to Dextenza. As of the filing of the lawsuit, Ocular's NDA for Dextenza had not yet been approved but Ocular intended to resubmit its NDA.[6]

II. Pleading Standard

"Section 10(b) of the Securities Exchange Act of 1934 forbids the 'use or employ, in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors.'" Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 318 (2007) (quoting 15 U.S.C. § 78j(b)) (alterations

[5] Although the plaintiffs allege a loss connected to the press release on July 12, 2017, the class period ends July 11, 2017.

[6] At the hearing on the pending motion, counsel for the defendants represented that Dextenza has since been approved.

and omission in original). In turn, SEC Rule 10b–5 implements § 10(b) by declaring it unlawful "in connection with the purchase or sale of any security" to "make any untrue statement of a material fact or to 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. Thus, to state a claim for securities fraud under Section 10(b), a plaintiff must plead: "(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 Biogen Inc. Sec. Litig., 857 F.3d 34, 41 (1st Cir. 2017) (citing Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 240 (1st Cir. 2015)).

As with any motion to dismiss, the Court must accept all well-pled factual allegations as true and draw all reasonable inferences in favor of the plaintiff.[7] See Tellabs, 551 U.S. at 322. To survive a motion to dismiss, the complaint must contain "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). As to allegations of fraud in particular, "plaintiffs must also meet the heightened pleading requirements imposed by the PSLRA, which requires plaintiffs to 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'" In re Biogen, 857 F.3d at 41 (quoting 15 U.S.C. § 78u-4(b)(1)); see also Greebel v. FTP Software, Inc., 194 F.3d 185, 193 (1st Cir. 1999) (describing the PSLRA's pleading standard as congruent with the Circuit's "notably strict and

[7] Additionally, the Court "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." See Tellabs, 551 U.S. at 322. The defendants in this case have attached various press releases, SEC filings, and transcripts of investor calls to their motion to dismiss. The plaintiffs do not contest the filing of these documents, and indeed, cites them in their opposition. Consequently, this memorandum considers the uncontested documents. See id.; Brennan v. Zafgen, Inc., 853 F.3d 606, 609–10 (1st Cir. 2017); N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 38 (1st Cir. 2008).

rigorous" application of Rule 9(b) of the Federal Rules of Civil Procedure in securities fraud actions).

The PSLRA also imposes a "rigorous pleading standard" for allegations of scienter, which encompasses a "mental state embracing intent to deceive, manipulate, or defraud." Abiomed, 778 F.3d at 240 (quotations omitted). The PSLRA requires plaintiffs to "state with particularity facts giving rise to a 'strong inference' that defendants" either "acted with a conscious intent 'to deceive or defraud investors by controlling or artificially affecting the price of securities' or 'acted with a high degree of recklessness.'" Id. "An inference of scienter is 'strong' if 'a reasonable person would deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Id. (quoting Tellabs, 551 U.S. at 324). "This standard may be met by 'clear allegations, internal records, or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendants were aware that they were withholding vital information,' or by a combination of 'various other facts and circumstances indicating fraudulent intent, including those demonstrating motive and opportunity.'" Mahoney v. Found. Med., Inc., 342 F. Supp. 3d 206, 213 (D. Mass. 2018) (quoting Brennan, 853 F.3d at 614 (internal quotations and citations omitted)). "When there are equally strong inferences for and against scienter, the draw is awarded to the plaintiff." Abiomed, 778 F.3d at 241 (quoting City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011)). "[S]cienter should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations." Id. (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 59 (1st Cir. 2008)).

III. Discussion

The defendants move to dismiss the complaint, arguing that the plaintiffs fail to allege an actionable misstatement or omission and that the allegations of the complaint do not support a strong inference of scienter.

A. Actionable Misstatement or Omission

i. *Challenged cGMP Statements on the 2016 and 2017 Forms 10-K*

The plaintiffs allege that the Company's attestations on its 2016 and 2017 Forms 10-K that it fabricates devices and drug depot products for its therapeutic product candidates "using current good manufacturing practices, or cGMP, at [its] multi-product facility in Bedford, Massachusetts" were materially false and misleading because the Company was not in fact in compliance with cGMP at the time the representations were made. As evidence for the statements' falsity, the plaintiffs rely primarily on the February 2016 Form 483, arguing that the defendants were informed about the Company's cGMP non-compliance prior to filing its 2016 Form 10-K.

Apart from the fact that the statements in the Forms 10-K were general statements untethered to any particular drug or investigation, the plaintiffs' factual allegations do not plausibly suggest that the Company's statements or omissions were materially false or misleading at the time they were made. The problem is that the statement about using cGMP is too general to do the specific work plaintiffs would like it to do. It is essentially a statement of the standards that the Company is guided by in designing and operating its manufacturing processes, much as a financial statement might say that it was prepared in accordance with generally accepted accounting practices. Neither statement should fairly be understood as a warranty that there have never been any instances of deviation from the standards. Rather, what is necessary are allegations of specific factual circumstances that show a deviation from the standard.

The plaintiffs do not allege any contemporaneous facts, such as emails, internal documents, or reports, to demonstrate that the Company in fact did not "us[e] current good manufacturing practices." Instead, they rely primarily on the Forms 483 to allege falsity. But, as those forms themselves state, the Forms 483 reflect only "inspectional observations" by the FDA representative, and "do not represent a final Agency determination regarding . . . compliance." (Kolovos Decl., Ex. E at 2; Second Kolovos Decl., Ex. A at 2.) See In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 42 (1st Cir. 2014) (describing "advisory language that accompanies all Forms 483, to the effect that the circumstances noted therein are merely observational in nature, and do not represent the FDA's final word"). And specifically, the particulate matter highlighted by the plaintiffs was not raised with the Company until the FDA's May 2017 Form 483—after both challenged statements in the Forms 10-K.[8]

In any event, the challenged statements about compliance with cGMP cannot be considered in isolation. It appears undisputable that the Company promptly disclosed its receipt of the two Forms 483. Ocular disclosed the receipt of the February 2016 Form 483 a month later in its 2016 Form 10-K, the very same filing the defendants contend contains an actionable statement about cGMP. In that filing, the Company stated:

> [I]n February 2016, as part of the ongoing review of our NDA for DEXTENZA, the FDA conducted a pre-NDA approval inspection of our manufacturing operations. As a result of this inspection, we received an FDA Form 483 containing inspectional observations focused on process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes. We addressed some observations before the inspection was closed and have responded to the FDA with a corrective action plan to complete the inspection process. . . . Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product

[8] Relatedly, allegations that the later issuance of the CRLs by the FDA show that these earlier generic statements were false or misleading amount to "fraud by hindsight," which has long been rejected as a basis for liability.

> approval, and would limit the availability of [our product] and our product candidates that we manufacture. The failure to resolve the Form 483 inspectional observations from the February 2016 inspection could result in a delay in the PDUFA date and potential approval for the NDA we have filed for DEXTENZA for the treatment of post-surgical ocular pain.

(Compl. ¶ 43; Kolovos Decl., Ex. A at 93.) Similarly, with respect to the May 2017 Form 483, Ocular issued a press release the next day disclosing its receipt, stating that the form contained "inspectional observations focused on procedures for manufacturing processes and analytical testing, relating to manufacture of drug product for commercial production." (Compl. ¶ 86.) It reported in its quarterly Form 10-Q on that date its plan to evaluate the observations and respond to the FDA with corrective action plans to complete the inspection process, and cautioned that "[a]dequate resolution of the outstanding Form 483 inspectional observations . . . is a prerequisite to the approval of the NDA." (Kolovos Decl., Ex. F at 31.) In the earnings call that same day, Ankerud disclosed that the primary focus of the May 2017 Form 483 related to a "particula[te] matter issue as part of [its] manufacturing process," the FDA's so-called "bombshell finding."[9] (Kolovos Decl., Ex. D at 8; Compl. ¶ 50.) If a reader were disposed to understand the general statement about cGMP as an assurance that the manufacturing process was free of defect, the specific disclosure of the receipt of the Forms 483 would have given the reader pause in persisting in that disposition.

The plaintiffs also take issue with the depth of information the company provided in their disclosures. They point to the share price drop after the publication of the *Seeking Alpha* report as evidence. The report, however, included not just factual information as to the details of the Forms 483, but also the publication's subjective and fairly colorful gloss on what the Forms meant. A

[9] The plaintiffs also contend that their confidential witness supports the falsity of the cGMP statement in 2017 Form 10-K. However, the plaintiffs have failed to allege a sufficient link between Ankerud's purported isolated admission about unspecified "batch records" months before the challenged cGMP statement on the 2017 Form 10-K to render the cGMP statement false.

company need not disclose immediately all information that "might conceivably affect stock prices." See In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012); accord In re Genzyme, 754 F.3d at 44 ("[A] corporation cannot be expected to inform the market of any and all developments that might possibly affect stock value."); Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 457 (1st Cir. 2017) ("The securities laws do not make it unlawful for a company to publicize an aggressive timeline or estimate for a proposed action without disclosing every conceivable stumbling block to realizing those plans."). "[T]he burden and risks to management of an unlimited and general obligation would be extreme and could easily disadvantage shareholders in numerous ways." In re Bos. Sci., 686 F.3d at 27–28.

ii. *Challenged Statement from November 9, 2016 Earnings Call*

The plaintiffs claim that Sawhney's statement during the November 9, 2016 call that "we've adequately we think addressed the issues that [the FDA] raised" was materially misleading because the Company misrepresented the nature and extent of the inspection deficiencies, omitted material negative facts regarding Ocular's manufacturing, and concealed material risks to Ocular's business. They argue that, to the extent that the statement was an opinion, it is nevertheless actionable because the information in Ocular's possession at the time regarding outstanding manufacturing deficiencies did not "fairly align" with the statement that it had resolved those deficiencies. See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 135 S. Ct. 1318, 1329 (2015).

Sawhney's statement is a protected statement of opinion. Sawhney prefaced his statement with "we think," signaling to investors that his statement was an opinion and not a guarantee. See Cody v. ConforMIS, Inc., 199 F. Supp. 3d 409, 419 (D. Mass. 2016) ("The statement appears to be an unvarnished opinion. Indeed, that is likely why 'we believe' was used, and a reasonable

investor would understand that.") Although statements of opinion or belief can be misleading, the plaintiffs have not adequately alleged that Sawhney did not in fact hold the stated opinion or omitted material facts that would lead an investor to doubt its reliability. See Omnicare, 135 S. Ct. at 1328–29; see also Sousa v. Sonus Networks, Inc., 261 F. Supp. 3d 112, 119 (D. Mass. 2017); ConforMIS, Inc., 199 F. Supp. 3d at 419 (D. Mass. 2016). The earnings call took place four months after Ocular had received the 2016 CRL, a time period during which Ocular had responded to the FDA and was engaged in ongoing conversations with regulators. Sawhney reminded the call participants that Ocular had received the 2016 CRL relating to manufacturing deficiencies, and he cautioned that the FDA would make a determination as to whether the Company had taken appropriate steps to address manufacturing-related issues after it resubmitted the NDA. Sawhney also noted that the FDA seemed to be "in broad agreement" with the Company's corrective plans that it had communicated to the FDA, in apparent reference to a letter Ocular had received from the FDA in the late summer "noting that the corrective actions detailed in the Company's responses as a whole appear to address the ten inspectional observations raised in the Form 483 with one exception." (Kolovos Decl., Ex. C at 6 (dkt. no. 68-3).) The plaintiffs have failed to plead that Sawhney's opinion did not "fairly align" with the information Ocular was aware of at the time or that the opinion was not honestly held by Sawhney. See Omnicare, 135 S. Ct. at 1329.

iii. *Challenged Statement from May 5, 2017 Earnings Call*

The plaintiffs challenge the statement made during the May 5, 2017 conference call that the Company "expect[ed]" to be able to resolve the problems identified in the May 2017 Form 483 "in a timely manner." (Kolovos Decl., Ex. D at 8.) They contend the statement was false and misleading because the defendants "knew, but failed to disclose, that the timing of the FDA

approval was in serious jeopardy because of the repeated unresolved observations outlining serious deficiencies in Ocular's manufacturing process of Dextenza." (Pls.' Opp'n 18.)

Ocular's statement that it expected to be able to resolve the issues identified on the May 2017 Form 483 in a "timely manner" is protected under the PSLRA's safe harbor provision. The PSLRA's "safe harbor" provision, 15 U.S.C. § 78u–5, "sharply limit[s] liability of companies and their management for certain 'forward-looking statements,' . . . when such statements are accompanied by appropriate cautionary language." In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d 68, 71 n.3 (1st Cir. 2012). Here, the Company's statement about its ability to resolve the problems identified in the May 2017 Form 483 in a timely manner was clearly a forward-looking forecast about a future event. Additionally, it was accompanied by appropriate cautionary language. At the outset, the Company stated:

> As a reminder, during today's call, we will be making certain forward-looking statements. Various remarks that we make during the call about the company's future expectations, plans and prospects do -- these do constitute forward-looking statements for purposes of the Safe Harbor provisions under the Private Securities Litigation Reform Act of 1995.
>
> Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the Risk Factors section of our most recent annual report or our actual report on Form 10-Q which was filed earlier this morning with the SEC. In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing our views as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our views change.

(Kolovos Decl., Ex. D at 1.)[10] Additionally, more specifically, Sawhney discussed the Form 483 and accurately cautioned that "timely resolution of the 483 observations is a prerequisite to keep the PDUFA date on track."[11] (Id. at 2.)

B. Scienter

The defendants also contend that even if the plaintiffs have adequately alleged an actionable false or misleading statement, the claims nevertheless still fail because the plaintiffs do not plead facts supporting a strong inference of scienter. The plaintiffs counter, claiming that the defendants knew about and recklessly disregarded the FDA's observations from the Forms 483 and their importance to the Dextenza NDA. They also argue that a Dextenza-related SEC investigation and the core operations doctrine further support a strong inference of scienter. Those contentions are non sequitors. The defendants knew about the 483s and disclosed them. There are no particular facts alleged to support the "reckless disregard" allegation. It is plain the defendants did not disregard the FDA's observations; they talked about them. The lone fact of an SEC investigation *after* the challenged statements proves nothing about scienter at the time of the statements. See Godinez v. Alere Inc., 272 F. Supp. 3d 201, 219 (D. Mass. 2017) (stating that "the existence of a subpoena does not, without more, give rise to a strong inference of scienter on the

[10] The referred to Form 10-Q included in its Risk Factors a description of the Dextenza-related FDA interactions, including the 2016 CRL, the new NDA, and the May 2017 Form 483, and cautioned specifically that "[a]dequate resolution of the outstanding Form 483 inspectional observations . . . is a prerequisite to the approval of the NDA for Dextenza" and that if "we are unable to resolve these inspectional observations in a timely manner, potential approval of the NDA would be delayed or prevented." (Kolovos Decl., Ex. F at 83–85); accord id. at 63.)

[11] At the hearing on the present motion, the plaintiffs briefly mentioned two other statements from the call. The first, regarding whether the Company envisioned a delay of the PDUFA, is not actionable for the same reason the statement about timeliness is not. The second, referring to Ocular's "fully developed manufacturing process," was made in the context of its *disclosure* of the Form 483 and the Company's effort to address the issues raised by the FDA. It is clear from context that "fully developed" was not a representation that it was "flawlessly developed."

part of senior management.") The core operations argument is nothing more than a rhetorical flourish, without supporting factual allegations. "Courts have been hesitant to apply significant weight to 'core operations' allegations without other significant evidence of a defendant's intent or recklessness, or a 'plus factor'." Metzler Asset Mgmt. GmbH v. Kingsley, 305 F. Supp. 3d 181, 219 (D. Mass. 2018) (quoting In re A123 Sys., Inc. Sec. Litig., 930 F. Supp. 2d 278, 285 (D. Mass. 2013)). Here, the plaintiffs do not allege a "plus factor" with respect to statements about cGMP compliance. See In re Psychemedics Corp. Sec. Litig., No. CV 17-10186-RGS, 2017 WL 5159212, at *6 (D. Mass. Nov. 7, 2017) (finding that the plaintiff's "core operations" theory "[stood] naked, unadorned by any other piece of evidence purporting to establish the essential 'plus' factor—guilty knowledge").

The plaintiffs make too much of the Individual Defendants' optimism by making conclusory allegations about Ocular's capacity to address the FDA's concerns. (See, e.g., Pls.' Opp'n 22 ("The nature of these deficiencies was such that timely remedy would have been a tremendous undertaking for Ocular, and rendered the FDA's approval of an NDA for, and thus future of, Dextenza unlikely and uncertain.").) They repeat allegations about the falsity of the statements, but ignore the disclosures about the Forms 483 made by the Company which undermine an inference of an intent deceive, see, e.g., In re Genzyme, 754 F.3d at 42–43, and overlook the progress the Company appears to have made in addressing the FDA's concerns, even from the FDA's perspective.[12]

[12] Further negating an inference of scienter is Sawhney's own *purchase* of shares during the class period. See Abiomed, 778 F.3d at 246. One might reasonably take that as a sign of his confidence in Ocular's ability to respond to FDA criticisms. One might not reasonably take it that he thought the Company was in such trouble that he had to feed the market misleading news.

IV. Claims against Individual Defendants

Section 20(a) provides for derivative liability by control persons for violations of the Exchange Act committed by others. Because the complaint fails to allege an underlying violation of the securities law, the derivative Section 20(a) claims also fail. See ACA Fin., 512 F.3d at 67–68.

V. Conclusion

For the foregoing reasons, the defendants' Motion to Dismiss the Consolidated Amended Class Action Complaint (dkt. no. 66) is GRANTED, and the case is DISMISSED.

It is SO ORDERED.

/s/ George A. O'Toole, Jr.
United States District Judge