United States Court of Appeals
For the First Circuit

No. 19-1557

KAVITA MEHTA; WILLIAM L. STEPHENS;
KHALED RAMADAN; OLEG TKALYCH,

Plaintiffs-Appellants,

THOMAS GALLAGHER, individually and on behalf of all others similarly situated; DYLAN CARAKER, individually and on behalf of all others similarly situated; SHAWNA KIM, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

OCULAR THERAPEUTIX, INC.; AMARPREET SAWHNEY;
ANDREW HURLEY; GEORGE MIGAUSKY; ERIC ANKERUD,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. George A. O'Toole, Jr., U.S. District Judge]

Before

Thompson, Stahl, and Barron,
Circuit Judges.

Jeremy A. Lieberman, with whom Austin P. Van, Pomerantz LLP, Robert V. Prongay, Kara M. Wolke, Glancy Prongay & Murray LLP, Glen DeValerio, Daryl Andrews, and Andrews DeValerio LLP were on brief, for plaintiffs-appellants.

Michael G. Bongiorno, with whom Peter J. Kolovos and Wilmer Cutler Pickering Hale and Dorr LLP were on brief, for defendants-

appellants.

April 9, 2020

STAHL, **Circuit Judge**. In September 2015, Ocular Therapeutix, Inc. ("Ocular" or the "company"), a public, Massachusetts-based biopharmaceutical company, submitted a New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") for approval of its drug product, Dextenza,[1] for treatment of ocular pain following ophthalmic surgery. After publication in July 2017 of the FDA's inspectional observations of issues at Ocular's manufacturing facility and a resultant drop in the company's stock price, several shareholders ("plaintiffs") initiated this securities fraud action against Ocular, its Chief Executive Officer, Amarpreet Sawhney, and its Executive Vice President of Regulatory, Quality, and Compliance, Eric Ankerud (collectively "defendants"), on behalf of themselves and a putative class of all other investors who had purchased or otherwise acquired the company's stock between March 10, 2016 and July 11, 2017 (the "class period").[2] Plaintiffs' two-count

[1] This opinion refers to the drug product at issue as "Dextenza" except where the name appears in cited materials as "DEXTENZA."

[2] The district court consolidated four related actions and appointed Kavita Mehta, William L. Stephens, Khaled Ramadan, and Oleg Tkalych as lead plaintiffs. Plaintiffs initially named Ocular's Chief Financial Officer, George Migausky, and its Chief Commercial Officer, Andrew Hurley, as additional defendants. However, plaintiffs subsequently did not contest defendants' assertion that the claims against Migausky and Hurley should be dismissed, and the district court dismissed all claims against them. Plaintiffs do not challenge the dismissal of those claims on appeal.

complaint alleged: first, that all defendants had on multiple occasions intentionally or recklessly misled investors about Ocular's manufacturing problems in violation of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b–5; and second, that Sawhney and Ankerud, as control persons for Ocular, were liable under Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

Defendants moved to dismiss the complaint for failure to state a claim pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), the Exchange Act, and the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. §§ 78u-4, 78u-5. The district court granted the motion and dismissed the complaint with prejudice. Plaintiffs timely appealed. We affirm, holding, on de novo review, that plaintiffs have not alleged facts giving rise to a strong inference of scienter as required by the PSLRA.

I. Background

A. Factual History

"We recite the facts as alleged in the complaint, supplemented by certain 'materials [the] defendants filed in the district court in support of their motion to dismiss.'" Brennan v. Zafgen, Inc., 853 F.3d 606, 609-10 (1st Cir. 2017) (alteration in original) (quoting Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 232 (1st Cir. 2015)). We also draw

from "documents the authenticity of which are not disputed by the parties," as well as "official public records; . . . documents central to plaintiffs' claim[s]; [and] documents sufficiently referred to in the complaint." Id. at 610 (alterations in original) (quoting Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993)).

Ocular, whose stock trades on the NASDAQ stock exchange, was founded in 2006. At its headquarters and multiproduct manufacturing facility in Bedford, Massachusetts, the company develops and commercializes therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel technology.[3] Dextenza is a drug-eluting medical implant, or plug, designed to be inserted into the tear duct of the eye, the canaliculus, through a natural opening, the punctum, located in the inner portion of the eyelid near the nose. Following insertion, Dextenza uses Ocular's proprietary hydrogel to provide sustained delivery of FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient to the surface of the eye and to act as an ocular tissue sealant. The production of Dextenza, like the other drug products manufactured at Ocular's multiproduct facility in Bedford,[4] is subject to, inter alia, the current Good

[3] Ocular is incorporated in Delaware.

[4] Ocular manufactured several drug products at its multiproduct facility in Bedford during the class period. Among

Manufacturing Practice ("cGMP") regulations regarding finished pharmaceuticals found in Part 211 of Title 21 of the Code of Federal Regulations. See generally 21 C.F.R. Part 211.

1. Ocular's 2015 NDA

In September 2015, Ocular submitted an NDA to the FDA seeking approval for the sale and marketing of Dextenza for treatment of ocular pain following ophthalmic surgery.[5] The FDA accepted the NDA for filing and established July 24, 2016 as the target date for action on the application under the Prescription Drug User Fee Act ("PDUFA"), 21 U.S.C. § 355.

In February 2016, as part of its reviewal of the NDA for Dextenza, the FDA inspected Ocular's manufacturing facility in Bedford for cGMP compliance. On February 11, the FDA delivered

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them were its drug product candidate OTX-TP, another hydrogel-based drug-eluting intracanalicular plug but with FDA-approved prostaglandin analogue travoprost as an active ingredient, developed as a treatment for glaucoma and ocular hypertension, and ReSure Sealant, a hydrogel-based post-surgical ophthalmic wound sealant approved by the FDA for commercial sale in 2014.

[5] According to the FDA, "[t]he NDA application [sic] is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA." FDA, New Drug Application (NDA), https://www.fda.gov/drugs/types-applications/new-drug-application-nda (last updated June 10, 2019). During the class period, Dextenza was in a Phase III clinical trial for the treatment of post-surgical ocular pain and inflammation, in a Phase III clinical trial for the treatment of allergic conjunctivitis, and in a Phase II clinical trial for the treatment of inflammatory dry eye disease.

its inspectional observations to Ocular's management on the agency's Form 483 ("February 2016 Form 483").[6] The February 2016 Form 483 provided ten observations detailing issues with Ocular's manufacturing facility, noting that they were "inspectional observations [that] do not represent a final agency determination regarding [Ocular's] compliance." The relevant portions of the FDA's observations were as follows:

Observation 1 stated that "[l]aboratory records do not include a complete record of all data secured in the course of each test, including all spectra from laboratory instrumentation, properly identified to show the lot tested and drug product tested."[7] See 21 C.F.R. §§ 211.180, 211.194(a).

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[6] FDA investigators issue a Form 483 to a company's management at the conclusion of an inspection when they have "observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act (FD&C) and related Acts." FDA, FDA Form 483 Frequently Asked Questions, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last updated Jan. 9, 2020).

[7] Observation 1.A specified that "[r]eview of [Ocular's] source documentation for analytical data submitted in [the] NDA . . . found that printed [high-performance liquid chromatography] chromatograms and integration results for dose content uniformity and purity were discarded . . . and only the reprocessed data was printed and retained." Review of that reprocessed data, per Observation 1.B.1, "revealed a failure to include the area of a typical peak of unknown impurity" at a given retention time "in the total area and content of unknown impurities." Observation 1.D noted that Ocular lacked "written procedures to clearly specify how manual integration of chromatograms is performed."

Observation 2 stated that "[s]amples taken of drug products for determination of conformance to written specifications are not representative," and that Ocular's "sampling plan supporting product release and stability testing . . . is not designed to assure that samples are representative of the entire subject lot or unit to be tested." See id. § 211.160(b)(1).

Observation 3 stated that "[c]ontrol procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product."[8] See id. § 211.100.

Observation 4 stated that "[a]ctual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of manufacturing of the drug product." See id. § 211.103. Observation 5 stated that "[w]ritten production and control procedures include batches formulated with the intent to provide [a certain] percent of the labeled or established amount of active ingredient." See id. § 211.101(a). Observation 6 stated that "[l]aboratory controls do not include the establishment of scientifically sound and

[8] As specified in Observation 3.D, Ocular "d[id] not characterize and trend rejects produced during inspection of drug product." See 21 C.F.R. § 211.180(e).

appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity." See id. §§ 211.160(b), 211.165.

Observation 7 stated that "[e]quipment for adequate control over air pressure, micro-organisms, humidity, and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product." See id. § 211.46. Observation 8 stated that "[t]ime limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product." See id. § 211.111. Observation 9 stated that "[u]nauthorized personnel have access to enter areas of the buildings and facilities designated as limited access areas," see id. § 211.28(c), while Observation 10 stated that "[b]uildings used in the manufacturing of a drug product are not maintained in a good state of repair," see id. § 211.58.

On March 10, 2016 -- the first day of the class period -- Ocular filed its Annual Report on Form 10-K ("2016 Form 10-K") for the year 2015 with the Securities and Exchange Commission ("SEC"). The company stated therein that it "fabricate[s] 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 [G]ood [M]anufacturing [P]ractices, or cGMP, at our multi-product facility located in

Bedford, Massachusetts." Ocular additionally disclosed its receipt of the February 2016 Form 483:

> [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.

In July 2016, the FDA sent Ocular a Complete Response Letter ("CRL") rejecting the NDA for Dextenza.[9] On July 25, Ocular issued a press release disclosing its receipt of the CRL and stating that "[t]he concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified

[9] The "FDA will send the applicant a [C]omplete [R]esponse [L]etter if the agency determines that [it] will not approve the application or abbreviated application in its present form for one or more of the reasons given in [21 C.F.R.] § 314.125 or § 314.127," which provide bases upon which the agency may refuse to approve an NDA. 21 C.F.R. § 314.110. The CRL rejecting the NDA for Dextenza was neither publicly released nor entered into the record of this proceeding.

during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility." That day, Ocular's share price fell $0.75, or 14.51%, closing at $4.42.

On November 9, 2016, Ocular held an earnings conference call with investors, during which defendant Sawhney 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.

Sawhney also stated:

> [W]hether or not re-inspection is required, is a determination that [the FDA] 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.

2. Ocular's 2017 NDA

On January 23, 2017, Ocular announced that it had resubmitted its NDA for Dextenza for the treatment of post-surgical ocular pain. On February 22, 2017, the company disclosed that the FDA had accepted the resubmitted NDA for filing and had designated July 19, 2017 as the target date for action on the application under the PDUFA.

On March 10, 2017, Ocular filed its Annual Report on Form 10-K ("2017 Form 10-K") for the year 2016 with the SEC. The 2017 Form 10-K essentially repeated the statement included in the 2016 Form 10-K that Ocular "fabricate[s] devices and drug insert and 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 multi-product facility located in Bedford, Massachusetts." The 2017 Form 10-K also noted that in the CRL Ocular had received in July 2016, "the concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of our manufacturing facility . . . in February 2016 that were documented on FDA Form 483."

The FDA reinspected Ocular's manufacturing facility from April 24 to May 4, 2017 as part of its reviewal of the resubmitted NDA for Dextenza. Following the reinspection, on May 4, the FDA issued to Ocular's management another Form 483 that identified six inspectional observations ("May 2017 Form 483").[10] In relevant part, the May 2017 Form 483 identified the following issues:

Observation 1 stated that "[w]ritten records are not always made of investigations into unexplained discrepancies," and specifically, that Ocular had "failed to investigate the nature of particulate matter that has been found in manufactured drug product." See 21 C.F.R. § 211.22(a). Further, "[p]articulate matter has been noted in 10/23 lots . . . manufactured from [February 2016] to [May 4, 2017]." As plaintiffs alleged, Ocular had determined sometime prior to April 28, 2017 that the particulate matter in the lots appeared to be inclusive of aluminum, which is toxic to humans if absorbed or consumed.

Observation 2 stated that "[w]ritten production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance." See id. §§ 211.22(d), 211.100(b). Specifically, Ocular had "not set critical parameters for defect

[10] Like its predecessor, the May 2017 Form 483 stated that it contained "inspectional observations [that] do not represent a final Agency determination regarding [Ocular's] compliance."

action limits, including but not limited to defects such as particulate matter, found within the drug product."[11]

Observation 3 stated that "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." See id. § 211.100(a). Observation 4 stated that "[t]he responsibilities and procedures applicable to the quality control unit are not in writing." See id. §§ 211.22, 211.188. Observation 5 stated that "[l]aboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity." See id. §§ 211.160(b), 211.165. Observation 6 stated that "[e]mployees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions." See id. § 211.25(a).

On the following day, May 5, 2017, Ocular released its financial results for the first quarter of 2017 in its Quarterly Report on Form 10-Q to the SEC. That morning, Ocular conducted a

[11] The FDA noted that three Dextenza batches -- from which 224 plugs, 45 plugs, and 37 plugs, respectively, had been rejected due to unknown particulate matter -- "were released for intended commercial use on [January 12, 2017] without critical defect limits established."

conference call with investors to discuss its disclosures and operations.[12] At the outset, Ocular's Chief Financial Officer, George Migausky, stated that "during today's call, we will be making certain forward-looking statements," and that "[a]ctual results may differ materially from those indicated by these forward-looking statements as a result of various important factors." Migausky also said that "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." During the call, defendant Sawhney disclosed that Ocular "received the Form 483 containing inspectional observations focusing on procedures for manufacturing processes and analytical testing related to manufacture of drug product for commercial production." Sawhney related the company's "plan to evaluate these observations and respond to the FDA in 15 days with corrective action plans to complete the inspection process," and noted that "[a] timely resolution of the 483 observations is a prerequisite to keep the PDUFA date on track." Subsequently, defendant Ankerud stated:

> FDA completed the re-inspection of our facility as part of the NDA review late yesterday afternoon. As Amar [Sawhney] mentioned, 483 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

[12] Beyond plaintiffs' allegations, we draw quotations from the full transcript of the May 5, 2017 conference call that defendants provided as an exhibit to their motion to dismiss the complaint. See Brennan, 853 F.3d at 609-10.

> 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 483 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 particula[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 483 as of this morning in anticipation of responding within 15 calendar days to the agency. In addition to the particula[te] 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.

Ankerud also stated:

> I think there is two important issues to recognize. The first is that from the prior preapproval inspection, FDA issued a 483. 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 [sic] 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.

Further, in response to an analyst's question of whether there was "anything in [the FDA's] observations that you think could delay the action date specifically," Sawhney replied:

> Nothing that we can currently see. I think these -- as you know, probably 90% plus inspections have 483. The question, what are 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.

Also on May 5, 2017, Ocular issued a press release that disclosed: "Following a re-inspection of manufacturing operations by the FDA . . . Ocular Therapeutix received an FDA Form 483 containing inspectional observations focused on procedures for manufacturing processes and analytical testing, related to manufacture of drug product for commercial production." Following the press release, the company's share price fell $1.47, or 16.15%, closing that day at $7.63.

On July 6, 2017, the website Seeking Alpha published an article titled "Ocular: A Poke in the Eye," which included links to the February 2016 and May 2017 Forms 483, making them public for the first time.[13] On the same day, STAT, a healthcare media outlet, published an article about Ocular suggesting that the FDA might reject the resubmitted NDA for Dextenza due to product

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[13] The article described the content of the Forms 483 and opined:

> Even a layperson reading [the May 2017 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.

The article further stated that observations in the February 2016 Form 483 were repeated in the May 2017 Form 483 and that observations in the second were worse than those in the first.

contamination, including aluminum, found during an agency inspection of the company's manufacturing facility. After the publication of the articles, Ocular's share price fell $3.06, or 30.06%, over the next two trading days, closing at $7.12 on July 7, 2017.

On July 12, 2017, Ocular received another CRL from the FDA rejecting the resubmitted NDA for Dextenza. That day, Ocular announced its receipt of the CRL in a press release, which stated that the FDA's rejection was based on "deficiencies in manufacturing processes and analytical testing related 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." Following this press release, Ocular's share price fell $0.93, or 12.24%, closing at $6.67 on July 12.[14]

[14] Plaintiffs alleged that the class period ended on July 11, 2017, one day before the loss that plaintiffs alleged was caused by Ocular's July 12, 2017 press release. Plaintiffs further alleged that on December 22, 2017 -- well after the class period ended -- Ocular issued a press release stating that it had received an SEC subpoena requesting "documents and information concerning DEXTENZA™ (dexamethasone insert) 0.4mg, including related communications with the FDA, investors and others." Further, plaintiffs alleged that Ocular had stated its intention to resubmit the NDA for Dextenza in the first half of 2018, and that the NDA had not been approved as of the date of the amended complaint, May 7, 2018. Counsel for defendants later represented that the FDA ultimately approved the NDA in late 2018.

B. Procedural Background

In July and August 2017, several plaintiffs filed putative class action lawsuits against defendants in the United States District Court for the District of New Jersey. Defendants successfully moved to transfer those actions to the District of Massachusetts. The district court consolidated the actions and appointed lead plaintiffs in March 2018. Plaintiffs filed their consolidated amended class action complaint on May 7, 2018. The complaint alleged two counts: first, that during the class period all defendants had on multiple occasions intentionally or recklessly misled investors by making false statements and omitting material facts about Ocular's manufacturing problems and the impact those problems were likely to have on the FDA's approval of Dextenza in violation of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b–5; and second, that Sawhney and Ankerud, as control persons for Ocular, were liable for the company's violations pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

On July 6, 2018, defendants moved to dismiss the complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), the Exchange Act, and the PSLRA. On April 30, 2019, the district court granted defendants' motion and dismissed the complaint with prejudice. See In re Ocular Therapeutix, Inc. Sec.

Litig., No. 17-12146, 2019 WL 1950399 (D. Mass. Apr. 30, 2019) ("Ocular I"). The district court determined that plaintiffs failed to allege an actionable misstatement or omission under Section 10(b) and Rule 10b-5 and that plaintiffs' allegations did not give rise to a strong inference of scienter in satisfaction of the PSLRA, 15 U.S.C. § 78u-4(b)(2)(A). Id. at *6-10. The district court also determined that plaintiffs' derivative Section 20(a) claim failed in the absence of an underlying securities violation. Id. at *10. Plaintiffs timely appealed the dismissal of both counts.

II. Discussion

On appeal, plaintiffs more narrowly argue that defendants' affirmative statements in the 2016 and 2017 Forms 10-K that Ocular manufactured Dextenza "using current Good Manufacturing Practices," and defendant Ankerud's two affirmative statements during the May 5, 2017 conference call that Ocular's manufacturing was "fully developed," were materially false and misleading. Plaintiffs further contend that a strong inference of scienter can be drawn from those alleged misstatements because defendants made them despite having received the February 2016 and May 2017 Forms 483 that apprised defendants of Ocular's manufacturing problems.

A. Standard of Review

We review de novo the district court's dismissal of a securities fraud complaint for failure to state a claim under Rule 12(b)(6). Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48, 56 (1st Cir. 2018). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Aschroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). In determining whether the complaint has done so, "we accept well-pleaded factual allegations in the complaint as true and view all reasonable inferences in the plaintiffs' favor." Kader, 887 F.3d at 56 (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008)). We may affirm the district court's dismissal of the complaint on any grounds supported by the record. Abiomed, 778 F.3d at 241 (citing Aldridge v. A.T. Cross Corp., 284 F.3d 72, 84 (1st Cir. 2002)).

B. Plaintiffs' Section 10(b) and Rule 10b-5 Claim Against All Defendants

Section 10(b) of the Exchange Act renders unlawful the "use or employ, in connection with the purchase or sale of any security registered . . . [of] any manipulative or deceptive device." 15 U.S.C. § 78j(b). Pursuant to the statute, Rule 10b-5 forbids any person "[t]o 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 the light of the circumstances under which they were made, not misleading . . . in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5. Therefore, to state a claim for securities fraud under Section 10(b) and Rule 10b-5, plaintiffs 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. Brennan, 853 F.3d at 613. The first and second elements are at issue in this appeal.

The heightened pleading standard of the PSLRA requires that complaints alleging securities fraud "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1); see also ACA Fin., 512 F.3d at 58 n.7 ("The PSLRA is consistent with this circuit's prior application of Federal Rule of Civil Procedure 9(b) to securities fraud actions, a standard which is 'notably strict and rigorous.'" (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 193 (1st Cir. 1999))).

As for scienter, which is "a mental state embracing intent to deceive, manipulate, or defraud," Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 319 (2007) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193-94 & n.12 (1976)), the PSLRA requires that complaints "state with particularity facts giving rise to a strong inference that the defendant acted with the

required state of mind," 15 U.S.C. § 78u–4(b)(2)(A). Here, plaintiffs must "show either that the defendants consciously intended to defraud, or that they acted with a high degree of recklessness." Kader, 887 F.3d at 57 (quoting Aldridge, 284 F.3d at 82). Recklessness involves "a highly unreasonable omission" constituting "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 and sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." Brennan, 853 F.3d at 613 (quoting Greebel, 194 F.3d at 198).

"To qualify as 'strong'" within the meaning of the PSLRA, "an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, 551 U.S. at 314. This Court "must consider the complaint in its entirety" and ask "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." Id. at 322-23. We have found this demanding standard met where a complaint "contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant[s] were aware that they were withholding vital

information or at least were warned by others that this was so." Brennan, 853 F.3d at 614 (alteration in original) (quoting In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012)).

Further, in undertaking this analysis, this Court "must consider, not only inferences urged by the plaintiff[s], . . . but also competing inferences rationally drawn from the facts alleged." Tellabs, 551 U.S. at 314. "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 Pol. & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011)).

We need not determine whether the allegedly misleading statements identified by plaintiffs constitute material misrepresentations because we find that the complaint, viewed holistically, failed to allege facts giving rise to a strong inference of scienter with respect to those alleged misstatements. See In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 750 (1st Cir. 2016).

1. Ocular's 2016 and 2017 Forms 10-K

We first assess plaintiffs' allegations that defendants intentionally or recklessly misstated in Ocular's 2016 and 2017 Forms 10-K that they "fabricate devices and drug . . . 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" despite the receipt of the February 2016 Form 483.[15] Read in the context of the complaint as a whole, these allegations do not give rise to a strong inference that defendants intentionally or recklessly misled investors.

As an initial matter, and as all parties acknowledge, the February 2016 Form 483 is not a final agency determination, and its inspectional observations did not affirmatively establish that Ocular was incapable of complying with cGMP regulations. Plaintiffs nevertheless contend that the February 2016 Form 483 placed defendants on notice of Ocular's manufacturing difficulties, compelling a strong inference that defendants intentionally or recklessly misled investors by subsequently stating in the Forms 10-K that they were "using current Good Manufacturing Practices" at their manufacturing facility. This argument is unpersuasive. In the two Forms 10-K, defendants disclosed receipt of the February 2016 Form 483, described its relevance to Ocular's manufacturing capabilities, and warned of

[15] Ocular's Forms 10-K were submitted in March 2016 and March 2017, after the company received the February 2016 Form 483 and before it received the May 2017 Form 483. Thus, plaintiffs' argument implicates only the February 2016 Form 483. See ACA Fin., 512 F.3d at 62 ("A plaintiff may not plead 'fraud by hindsight'; i.e., a complaint 'may not simply contrast a defendant's past optimism with less favorable actual results' in support of a claim of securities fraud." (quoting Shaw v. Dig. Equip. Corp., 82 F.3d 1194, 1223 (1st Cir. 1996))).

its implications. Defendants stated in both Forms 10-K, under Item 1A, "Risk Factors," and the subheading "Risks Related to Manufacturing," that the February 2016 Form 483 contained "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." (Emphasis added). Defendants also stated that they "addressed some observations before the inspection was closed and [had] responded to the FDA with a corrective action plan to complete the inspection process." (Emphasis added). Among these statements, defendants cautioned that "[a]ny 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 candidates that we manufacture."

More specifically, in the 2016 Form 10-K, defendants clarified that "[t]he 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." (Emphasis added). In the 2017 Form 10-K, submitted months after the FDA rejected Ocular's September 2015 NDA, defendants specifically noted that "the concerns raised by the FDA" in the

CRL rejecting the NDA "pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of our manufacturing facility . . . in February 2016 that were documented on FDA Form 483." (Emphasis added). Defendants further stated that "[a]dequate resolution of Form 483 manufacturing deficiencies with the [FDA] is a prerequisite to the approval of the NDA for DEXTENZA." (Emphasis added).

These informative disclosures about the nature and consequences of the February 2016 Form 483 undercut any inference that defendants intentionally or recklessly misled investors by stating, in the same Forms 10-K containing those disclosures, that they were "using current Good Manufacturing Practices" at their manufacturing facility. See Abiomed, 778 F.3d at 243-44 (holding that scienter argument was undercut by a company's disclosure to investors of correspondences with the FDA and potential consequences of the agency's negative determination); In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 42-43 (1st Cir. 2014) (holding that company's informative disclosures, including of a Form 483 and other FDA communications, "undercut any inference of fraudulent intent on the part of defendants"); Waters Corp., 632 F.3d at 760 ("[A]ttempts to provide investors with warnings of risks generally weaken the inference of scienter." (alteration in original) (quoting Ezra Charitable Trust v. Tyco Intern., Ltd., 466 F.3d 1, 8 (1st Cir. 2006))).

Assuming arguendo that any inference of scienter could be drawn from the complaint's allegations regarding defendants' statements in the Forms 10-K, that inference is not "at least as compelling as any opposing inference of nonfraudulent intent" such that it is sufficiently "strong" under the PSLRA. Tellabs, 551 U.S. at 314. Here, given defendants' statements in the two Forms 10-K that they produce multiple products at their Bedford manufacturing facility "using" cGMP, and in light of the informative disclosures regarding the February 2016 Form 483, the more reasonable inference of nonfraudulent intent is that defendants were stating their intention to comply with cGMP regulations as the governing standards for their drug product manufacturing operations. See Abiomed, 778 F.3d at 240 (holding that materiality and scienter inquiries are linked and that a fact is material where there is a "substantial likelihood" that a reasonable investor would view it as "significantly alter[ing] the total mix of information made available" (alteration in original) (quoting Waters Corp., 632 F.3d at 756)); see also Singh v. Cigna Corp., 918 F.3d 57, 60-64 (2d Cir. 2019) (holding that a reasonable investor would not rely on statements in two Forms 10-K that a company "expect[s] to continue to allocate significant resources" to various compliance efforts as representations of satisfactory compliance without more detail (alteration in original)). Thus,

reading the complaint as a whole, we determine that these allegations do not give rise to a strong inference of scienter.[16]

2. The May 5, 2017 Conference Call

We turn to plaintiffs' allegations that defendant Ankerud intentionally or recklessly misled investors during the May 5, 2017 conference call by twice stating that Ocular's manufacturing process was "fully developed" despite the receipt of the May 2017 Form 483 one day before and the earlier receipt of the February 2016 Form 483 showing that Ocular had manufacturing problems. Read in the context of the entire complaint, these allegations also do not give rise to a strong inference of scienter.

[16] Plaintiffs alleged that a confidential witness had a direct conversation with Ankerud in late 2016 or early 2017, prior to Ocular's NDA resubmission, in which "Ankerud expressly acknowledged that he and the Company knew Ocular would be including batch records in the NDA resubmission that would not meet FDA standards." Plaintiffs also alleged that the witness's statements "make clear that Ocular and the Individual Defendants were aware of the severity of the problems Ocular faced in manufacturing DEXTENZA using cGMP." Before the district court, plaintiffs specified that these allegations concerned only their contention regarding the 2017 Form 10-K. Plaintiffs now reference those allegations in support of their scienter argument. This contention is unpersuasive. Plaintiffs do not now challenge the district court's finding that the complaint "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." Ocular I, 2019 WL 1950399 at *7 n.9. Thus, these confidential witness allegations do not disrupt our determination that the complaint, read as a whole, does not allege facts giving rise to a strong inference of scienter.

On the conference call, after defendant Sawhney's disclosure that Ocular had "received the [May 2017] Form 483 containing inspectional observations focusing on procedures for manufacturing processes . . . of drug product for commercial production," Ankerud spoke about the Form 483's contents and implications as well as the company's need to pursue remediation. (Emphasis added). Ankerud specified that the FDA's "primary focus in the 483 relates to a particula[te] matter issue as part of our manufacturing process" and that it also contained observations regarding "analytical method, testing to be completed, as well as some other issue related to quality oversight of batch records." (Emphasis added). Following this disclosure, Ankerud stated that defendants "believe that each of the observations raised by the FDA during this continuous improvement review of our fully developed manufacturing process are handled well and will be resolved in our response to FDA. . . . and we're marching toward that PDUFA date and expect that we can resolve the 483 issues in a timely manner." (Emphasis added). Ankerud subsequently stated that "the 483 is something that we have to respond to . . . . [W]e understand where [the FDA is] coming from and what needs to be done to address their concern." Afterwards, in response to an analyst's request for "something you can tell us or say to us in terms of how things have evolved at the company overall and oversight of manufacturing," Ankerud stated that "the

manufacturing process has moved forward significantly, and is in a fully developed mode," and that "the new investigator was experienced in the pharmaceutical industry and we had good dialog and good discussion and that's why we felt confident that we can address these 483 issues in a timely manner." (Emphasis added).

Ankerud's disclosures regarding the May 2017 Form 483 made pellucid that Ocular's manufacturing process was considered deficient by the FDA and thus undercut any inference that he intentionally or recklessly misled investors by stating that Ocular's manufacturing process was "fully developed." See Abiomed, 778 F.3d at 243-44; Genzyme Corp., 754 F.3d at 42-43; Waters Corp., 632 F.3d at 760.[17] Defendants submit that according to the FDA, a "fully developed" process is one that has surpassed the concept or piloting stage but must still be tested and validated to determine whether the process works as intended and meets the necessary standards. See FDA, Guide to Inspections of Medical Device Manufacturers at § 7 (2014) ("The process must be developed before it can be validated. . . . It is impossible to

[17] We reject plaintiffs' argument that defendants' disclosures of the February 2016 and May 2017 Forms 483 in the Forms 10-K and the May 5, 2017 conference call did not sufficiently inform investors that the Forms 483 documented "major" rather than "minor" problems in Ocular's manufacturing operations. Plaintiffs provide no legal support for their speculative assertion that the issues observed by the FDA and recorded in the Forms 483 were so major that they rendered nugatory defendants' disclosures and ultimately compel a strong inference of scienter.

validate a process (i.e. show that it consistently operates within established parameters and produces results or products that meet specifications) until the process is fully developed."), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/page-9. We may consider that fact. See Brennan, 853 F.3d at 609-10; Tellabs, 551 U.S. at 322 ("[C]ourts 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 . . . matters of which a court may take judicial notice."). In light of that term of art and Ankerud's disclosures during the conference call that contravene plaintiffs' characterization of his statements, the more reasonable and compelling inference drawn from the complaint's allegations is that Ankerud spoke with nonfraudulent intent in describing Ocular's manufacturing process as "fully developed." See Tellabs, 551 U.S. at 314.

Overall, reading the complaint as a whole, we determine that plaintiffs have not alleged facts giving rise to a strong inference of scienter as required by the PSLRA.[18] Thus,

[18] The district court correctly determined that defendant Sawhney's purchase of Ocular shares during the class period somewhat "[f]uther negat[es] an inference of scienter," at least as to Sawhney and Ocular. Ocular I, 2019 WL 1950399 at *10 n.12; see Abiomed, 778 F.3d at 246 (holding that an individual defendant's purchase of company stock during the class period "negates any inference that he had a motive to artificially inflate [the company's] stock during that period"); cf. Tellabs, 551 U.S.

plaintiffs' securities fraud claim brought under Section 10(b) and Rule 10b-5 fails.

C. Plaintiffs' Section 20(a) Claim Against Individual Defendants

Section 20(a) of the Exchange Act imposes joint and several liability on persons in control of entities that are liable for violations of securities laws "unless the controlling person[s] acted in good faith and did not directly or indirectly induce the act or acts constituting the violation." 15 U.S.C. § 78t(a). A claim brought under Section 20(a) is thus derivative of a claim alleging an underlying securities law violation. See Abiomed, 778 F.3d at 246. Accordingly, because the complaint does not state a securities fraud claim under Section 10(b) and Rule 10b-5, plaintiffs' derivative claim under Section 20(a) too must fail. See id.

III. Conclusion

The district court properly dismissed plaintiffs' primary Section 10(b) and Rule 10b-5 claim and derivative Section 20(a) claim. We therefore AFFIRM the judgment of the district court.

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at 325 ("While it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference, . . . the absence of a motive allegation is not fatal."). Viewed in the context of the complaint as a whole, this fact is consistent with our conclusion that plaintiffs have not alleged facts giving rise to a strong inference of scienter.