UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SAMANTHA WHITEHEAD, individually and on behalf of all others similarly situated,	)	
Plaintiff,	)	
v.	)	Case No. 17-cv-10025-LTS
INOTEK PHARMACEUTICALS CORPORATION, DAVID SOUTHWELL, and RUDOLF BAUMGARTNER,	)	
Defendants.	)	

ORDER ON MOTION TO DISMISS SECOND AMENDED COMPLAINT

June 27, 2018

SOROKIN, J.

This class action case, brought by and on behalf of Lead Plaintiff Brian Gniadek[1] and other similarly situated holders of the common stock of Inotek Pharmaceuticals Corporation ("Inotek"), alleges Inotek and two of its officers, David Southwell and Rudolf Baumgartner,[2] violated securities laws by issuing materially false and misleading statements and omitting to state material facts in press releases, corporate presentations, a Prospectus, and on a Form 10-K. Doc. No. 40. The Defendants filed a joint Motion to Dismiss, Doc. No. 42, and the Gniadek class ("Gniadek") opposed, Doc. No. 46.

[1] The class action was originally brought by Samantha Whitehead. Doc. No. 1. Whitehead and Gniadek moved to appoint Gniadek as Lead Plaintiff, and thereafter the Court appointed Gniadek to be Lead Plaintiff. Doc. Nos. 11; 24.

[2] Southwell is the President and Chief Executive Officer of Inotek and a member of the Inotek board of directors. Doc. No. 40 at ¶ 21. Baumgartner is the Executive Vice President and Chief Medical Officer of Inotek. Id. at ¶ 22. Defendants Southwell and Baumgartner are, hereinafter, referred to as the Officer Defendants.

I. THE COMPLAINT'S ALLEGATIONS

A. FACTUAL ALLEGATIONS[3]

Inotek is a clinical-stage biopharmaceutical company located in Massachusetts that focuses on the development and commercialization of novel therapies for diseases of the eye. Doc. No. 40 at ¶ 2. The Gniadek class are persons who purchased Inotek common stock between July 23, 2015 and July 10, 2017 ("the Class Period"). Id. at ¶ 1.

During the class period, Inotek had only one product candidate, trabodenoson ("trabo")—a potential therapy for glaucoma—for which Inotek was attempting to receive approval from the Food and Drug Administration ("FDA") to market as both a monotherapy (to be used in isolation) and as a fixed-dose combination (to be co-administered with another FDA approved drug). Id. at ¶¶ 2-3.[4] If approved, trabo would be marketed and used to reduce intraocular eye

[3] In considering the Defendants' motion to dismiss, the Court must accept the Complaint's factual allegations as true and draw all reasonable inferences in Plaintiffs' favor. Saldivar v. Racine, 818 F.3d 14, 16 (1st Cir. 2016). Unless otherwise noted, all facts are recited as set forth in the Complaint. The Defendants' motion is accompanied by sixteen exhibits, Doc. No. 44-1-44-16, including SEC filings, risk disclosures, and communications referred to in the Complaint. While ordinarily "any consideration of documents not attached to the complaint, or not expressly incorporated therein, is forbidden ... courts have made narrow exceptions for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; [and] for documents sufficiently referred to in the complaint." Watterson v. Page, 987 F.2d 1, 3 (1st Cir.1993). SEC filings, risk disclosures, and undisputed communications referenced in the complaint are the sorts of documents courts routinely consider at the Motion to Dismiss stage. See, e.g., Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 232 n. 2 (1st Cir.2015). Plaintiff has not objected to the consideration of these documents. Accordingly, the Court will consider the submitted exhibits where indicated.

[4] "The FDA requires any drug to go through a series of clinical trials before it can be approved for marketing and sales in the United States." New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 39 (1st Cir. 2008). Human testing "typically follows three phases": Phase I studies, which involve fewer than one hundred subjects and are "designed to determine how [a] drug works in humans[;]" Phase II studies, which usually involve several hundred subjects and are "designed to evaluate the effectiveness of the drug, as well as common short-term . . . risks[;]" and Phase III studies, which are "large-scale trials, usually involving

pressure in patients with glaucoma with more convenient dosing than treatments currently available in the market. Id. at ¶¶ 2-3, 7.

In preparation for its application to the FDA for approval to market and sell trabo, Inotek conducted a series of clinical trials: a Phase I trial, three Phase II trials, and a Phase III trial. See Doc. No. 40 at ¶¶ 4-5, 8, 55, 64. Inotek's first Phase II trial, which was completed in 2012, studied whether different doses of the trabo monotherapy—trabo administered in isolation without any other drugs or additives—demonstrated a statistically significant improvement over a placebo in treatment of glaucoma. Id. at ¶¶ 4, 64. The trial showed that 200 mcg [i.e., micrograms] and 500 mcg doses of trabo, when administered twice daily ("BID[5] doses"), outperformed the placebo, but that BID doses of 50 or 100 mcg did not. Id. at ¶ 64. The trial also showed that, after four weeks of BID dosing, trabo's beneficial effects "persisted for an additional 24 hours after the last dose of medication." Doc. Nos. 46-1 at 17; 44-1 at 17. The trial did not investigate the efficacy of trabo when administered once daily ("QD doses"). Doc. No. 40 at ¶ 64.

In 2014, Inotek initiated a second Phase II trial, this one investigating the effectiveness of trabo when co-administered with latanoprost ("latan"), an FDA approved glaucoma therapy. Id. at ¶ 66. This trial showed that BID dosing of trabo co-administered with latan was statically superior to latan administered in isolation but statistically inferior to the combination of timolol (another glaucoma therapy) with latan. Id. at ¶ 68; Doc. No. 44-6 at 15.

several hundred to several thousand subjects, and are intended to gather the information necessary to provide an adequate basis for labeling the drug." Id.

[5] "BID" comes from the Latin "bis in die," twice a day. *B.I.D.*, MedTerms Medical Dictionary (2016), available at https://www.medicinenet.com/script/main/art.asp?articlekey=6954.

In 2015, armed with the results of the first two Phase II studies, the FDA gave Inotek permission to proceed with a Phase III trial of the trabo monotherapy ("the MATrX-1 study"), which was to compare the effects of a placebo; timolol; and various QD doses of trabo over a three month period. Id. at ¶ 5, 64, 69-71. At this time, Inotek disclosed all of the results of the first two Phase II trials in its publically available filings with the SEC. Doc. Nos. 44-2; 44-4; 44-5; 44-6.

Inotek then issued several press releases, claiming, *inter alia*, "Our previous Phase II studies have demonstrated that [trabo's] efficacy improves over time[,]" "If approved, trabodenoson—with its potential for once daily dosing . . . has potential as a valuable treatment option[,]" and held a conference call during which the Officer Defendants stated that "in our Phase II study, we showed very good statistical significance of lower doses to placebo." Id. at ¶¶ 85, 89, 93. In March of 2016, Inotek filed a Form 10-K making similar statements, such as "clinical trials have shown that [trabo] has . . . convenient dosing," and positive effects "in line with existing therapies" with "potential to be used as a monotherapy." Id. at ¶¶ 98. In July 2016, Southwell gave a presentation again referencing trabo's "ability to dose QD or BID," and Baumgartner discussed the potential for trabo co-administered with latanoprost "to provide patients and physicians with a novel treatment option that offers the convenience of a single daily drop[.]" Id. at ¶¶ 101-02.

In July of 2016, while conducting its Phase III trial, Inotek initiated a third Phase II trial studying the effects of various fixed doses of trabo and latan administered in a single combination dose ("a single daily drop"). Id. ¶¶ 73-74.

Throughout the period in which Inotek was conducting the third Phase II trial and the Phase III trial, Inotek continued to issue statements expressing optimism about trabo. Inotek

issued a Prospectus ("the Prospectus") stating that trabo monotherapy has "effects in line with existing therapies" and that a Phase II clinical trial indicated that trabo co-administered with latanoprost demonstrated benefits "in patients who have previously had inadequate responses to treatment with latanoprost." Id. at ¶ 105. In a November 2016 presentation, Inotek again touted the ability of trabo to dose QD or BID. Id. at ¶ 106.

On January 3, 2017, Inotek issued a press release that the first Phase III trial "did not achieve its primary endpoint," i.e. demonstrating that trabo was more effective at reducing intraocular eye pressure than a placebo. Id. at ¶ 108. Following this disclosure, the price of Inotek common stock declined approximately seventy percent. Id. at ¶ 110.

Following the disappointing January 3, 2017 announcement, Inotek issued a series of statements expressing optimism about trabo. On March 16, 2017, Inotek filed its Form 10-K for the 2016 year stating that its first Phase II additive study showed that trabo benefited patients who had "previously had inadequate responses to latanoprost." Id. at ¶ 112; see supra at (discussing the results of the Phase II additive study, which "showed that BID dosing of trabo co-administered with latan was statically superior to latan administered in isolation"). That same day Inotek issued a press release admitting that the Phase III trial "did not achieve its primary endpoint," but expressing the view that "this result was driven by placebo outliers[,]"[6] and that Inotek "expected to report top-line data in mid-2017." Doc. No. 40 at ¶¶ 114, 119. Defendant Southwell expressed similar optimism in an April 2017 press release in which he said, "[W]e continue to believe our [product] has the potential to . . . provide patients with a novel treatment option[.]" Id. at ¶ 120. The press release also described trabo as "a highly selective adenosine

[6] Inotek's disclosed the basis for its hypothesis that its negative Phase III trial results were driven by placebo outliers: a variation in placebo responses between its Phase II and Phase III trials. See Doc. No. 44-11 at 6.

mimetic that lowers intraocular pressure (IOP)[.]" Id. at ¶ 122. On May 10, 2017, Inotek again expressed a hope as to "top-line results from [the third Phase II study.]" Id. at ¶ 124.

On July 7, 2017, Inotek released the results of the third Phase II study in a press release: trabo co-administered with latan offered no "clinically meaningful advantage . . . over [latan] alone." Id. at ¶ 127. Following this announcement, between Friday, July 7 and Monday, July 10, the share price of Inotek dropped nearly forty-eight percent. Id. at ¶ 128. On August 3, 2017, Inotek issued a press release announcing that they had "decided to discontinue all preclinical and clinical development activities associated with [trabo.]" Id. at ¶ 129.

B. LEGAL CLAIMS

First, Gniadek claims the Defendants violated Section 10(b) of the Securities Exchange Act of 1934 ("the Exchange Act"), 15 U.S.C. § 78j(b), and SEC Rule 10b-5 promulgated thereunder, 17 CFR § 240.10b-5, by disseminating or approving false and misleading statements by which they deceived and defrauded shareholders (Count I). Doc. No. 40 at ¶¶ 154-62. Second, Gniadek alleges the Officer Defendants violated Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), because they exercised control over Inotek during the time that Inotek violated Section 10(b) (Count II). Id. at ¶¶ 163-67.

II. DISCUSSION

Faced with a Rule 12(b)(6) motion to dismiss a securities fraud claim, "courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007). However, "Congress has raised the standard of pleading for Section 10(b) and Rule 10b-5 securities fraud claims." City of Bristol Pension Fund v. Vertex Pharm. Inc., 12 F. Supp. 3d 225, 234 (D. Mass. 2014); accord Local No. 8 IBEW Ret. Plan v. Vertex Pharm.

Inc., 140 F. Supp. 3d 120, 129 (D. Mass. 2015), aff'd sub nom. Local No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharm., Inc., 838 F.3d 76 (1st Cir. 2016). Under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), when a plaintiff alleges a material misrepresentation or omission of a material fact, the complaint must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading," and "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)(1)-(2). To qualify as "strong," "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, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007). In assessing whether scienter has been properly alleged, a court must "look[] at the complaint as a whole." New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 45 (1st Cir. 2008). It "must weigh not only inferences urged by the plaintiff but also competing inferences rationally drawn from the facts alleged." Id. "If there are equally strong inferences for and against scienter, then the tie goes to the plaintiff." Local No. 8, 140 F. Supp. 3d at 130 (citing New Jersey Carpenters, 537 F.3d at 45).

A. Section 10(b)/Rule 10b-5 Claims

Count I alleges violations of SEC Rule 10b-5, promulgated pursuant to Section 10(b) of the Exchange Act. SEC Rule 10b-5 prohibits, "within the context of the purchase or sale of any security," the employment of "any device, scheme, or artifice to defraud;" the issuance of "any untrue statement of a material fact or [omission] 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;" or the engagement "in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person." 17 C.F.R. § 240.10b-5. To prevail on a

claim under SEC Rule 10b-5, a plaintiff must show "(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." Hensley v. Imprivata, Inc., 2017 WL 2178644, at *7 (D. Mass. May 16, 2017). "The required state of mind for liability under section 10(b) . . . is referred to as *scienter*, which the Supreme Court has defined as 'a mental state embracing intent to deceive, manipulate, or defraud.'" Greebel v. FTP Software, Inc., 194 F.3d 185, 194 (1st Cir. 1999) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)).

Gniadek has alleged Inotek made numerous statements with material misrepresentations or omissions of material facts. See Doc. Nos. 46-1; 40. The omissions and misstatements alleged by Gniadek fall into four categories: (1) statements concerning the future of trabo; (2) selective reporting of Phase II results and lack of dosage information; (3) statements concerning QD trabo's relative performance; and (4) statements concerning QD dosing convenience. See Doc. No. 40 at ¶¶ 77-106, 112-25. Gniadek's allegations are insufficient for two reasons. First, Gniadek has not adequately alleged *scienter*. Second, the alleged statements and omissions are not are not materially false or misleading.

1. *Scienter*

The PSLRA's rigorous pleading standards require that a plaintiff allege facts raising a "strong inference" of *scienter*. See Corban v. Sarepta Therapeutics, Inc., 868 F.3d 31, 37 (1st Cir. 2017). A plaintiff must allege particularized facts that show "either conscious intent to defraud or a high degree of recklessness." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). Under the PLSRA, recklessness "involves . . . 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 the actor must have been aware of it." Brennan v. Zafgen, Inc., 853 F.3d 606, 613 (1st Cir. 2017).

Gniadek presents two reasons to infer *scienter* here: (1) "Defendants undeniably knew the results from the Phase 2 trials[,]" Doc. No. 46 at 17; and (2) "[T]rabo was Inotek's only product and was undeniably vital to its future success." Id. at 26. Inotek does not deny that they knew of the results of the Phase 2 trials. Inotek knew of the results and disclosed them. Supra at 3. Nor does Inotek deny that the success of trabo was vital to its future success. This, however, is not enough to infer conscious intent to defraud or an extreme departure from the standard of ordinary care. As the First Circuit has instructed:

> [T]he dispute here is not about whether the facts alleged support the inference that the defendants knew of certain undisclosed facts during the class period. We addressed that type of scienter question in *New Jersey Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 44 (1st Cir.2008). Rather, the question here is whether there is a strong inference that the defendants' failure to disclose certain facts was a result of wrongful intent, or scienter, even assuming defendants knew of those facts. Answering this question involves an inquiry into the relationship between scienter and the materiality of the undisclosed information.
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> City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 753 (1st Cir. 2011)

Thus, the relevant question is not whether Inotek knew the results of the Phase II trials but whether Inotek chose to conceal or misstate the results knowing their statement posed a risk of misleading investors "such that they therefore acted intentionally or recklessly by not disclosing [or misstating] them." Brennan v. Zafgen, Inc., 199 F. Supp. 3d 444, 466 (D. Mass. 2016), aff'd, 853 F.3d 606 (1st Cir. 2017). Such an inference is not possible here where the very information that Gniadek asserts Inotek intended to conceal or misstate was fully disclosed in Inotek's SEC filings. Furthermore, "[c]atch-all allegations' which merely assert motive and opportunity, without something more, fail to satisfy the PSLRA." Id. (quotations omitted). Only

when "financial incentives to exaggerate . . . go far beyond the usual arrangements . . . [may] they be considered among other facts to show *scienter*." Aldridge v. A.T. Cross Corp., 284 F.3d 72, 83 (1st Cir. 2002). That Inotek was a "one-drug company" is not such an unusual arrangement. See Zafgen, 199 F. Supp. 3d at 466 (finding allegations of motive insufficient to infer *scienter* when plaintiff alleged defendant was "a one-drug company" who "knew they would rise or fall based solely on [one drug]'s future.").

For the forgoing reasons, even after drawing all reasonable inferences on behalf of Gniadek, the Complaint falls short of alleging a strong inference of intentional or reckless misstatements or omissions as required by the PSLRA. Accordingly, Count One is DISMISSED.

2. *Statements concerning the future of trabo*

Although Gniadek's failure to properly allege *scienter* is sufficient on its own for dismissal, in an abundance of caution, the Court also addresses the statements and omissions that Gniadek has alleged are false or misleading. In the Complaint, Gniadek alleges that Inotek issued statements concerning the future of trabo that were false and misleading. See, e.g., supra at 5 ("[W]e continue to believe our [product] has the potential to . . . provide patients with a novel treatment option . . ."); Doc. No. 40 at ¶ 120 ("[W]e continue to believe our FDC program has the potential to address a larger market . . ."). These statements are non-actionable statements protected by the PSLRA's "safe harbor" for forward-looking statements. See 15 U.S.C.A. § 78u-5(c)(1)(A), (B).

The PSLRA's safe harbor "has two alternative inlets: the first shelters forward-looking statements that are accompanied by meaningful cautionary statements. The second . . . precludes liability for a forward-looking statement unless the maker of the statement had actual knowledge it was false or misleading." Greebel, 194 F.3d at 201. Here, the alleged forward looking statements fall within the protections of the safe harbor because, first, many (if not all) of

the alleged statements were accompanied by cautionary warnings. E.g. Doc. No. 44-1 at 2 ("This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties . . ."); id. at 10 ("[T]here can be no assurance that we will be able to pursue further development efforts or obtain regulatory approval."); id. ("We have no other product candidates in our near term product pipeline. As a result, we are substantially dependent on the successful development and commercialization of trabodenoson."). Second, Gniadek has not sufficiently alleged these statements were made with "actual knowledge" that they were false or misleading.

Gniadek asserts two reasons to infer actual knowledge: (1) Defendants had knowledge of certain negative outcomes in earlier trials; (2) Defendants had a motive to deceive—desire to raise capital. Doc. No. 46 at 16. This is not enough; these two points do not support an inference of actual knowledge "*at least* as compelling as any plausible opposing inference one could draw." Tellabs, 551 U.S. at 310 (emphasis added). Moreover, although the first two Phase II trials demonstrated some negative results, the trials also showed some positive results, including certain doses of trabo outperforming a placebo and trabo having continued benefits for twenty-four hours after use. Supra. at 3. The results were sufficiently positive that Inotek invested in a Phase III trial. See Local No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharm., Inc., 838 F.3d 76, 81 (1st Cir. 2016) (noting that when a pharmaceutical company has "made the investment necessary to design and perform a study," the company "must have thought that positive results were possible, even if not probable."). Id. Furthermore, the FDA authorized Inotek to proceed to a Phase III trial. Supra at 4. It is certainly plausible that Inotek and the Officer Defendants were in fact optimistic because of these positive results and expressed their sincere view as to the future of trabo. Gniadek has alleged no evidence that makes the opposite inference as or more compelling. Accordingly, these statements fall within the safe harbor's protection.

3. *Selective Reporting of Phase II results and Lack of Dosage Information*

Gniadek also alleges that Inotek made a series of statements about the results of the first two Phase II trials and that these statements were false and misleading because they omitted certain negative results[7] and information that remained unknown.[8] See Doc. No. 32 at 43-47. For instance, Gniadek alleges that Inotek's statement that the Phase II studies "demonstrated that [trabo's] efficacy improves over time, and with increases in dose" was false or misleading because it omits to state (1) timolol with latan outperformed trabo with latan in one trial and (2) neither trial studied the impact of the trabo monotherapy dosed QD. See Doc. No. 32 at 43. These omissions are not misleading; how trabo compares to other drugs on the market or the number of times per day that trabo will be administered is not implied by a statement about trabo's efficacy overtime—those things were simply not the subject of the statement. Furthermore, the omissions are not "material," as required by Section 10(b) because the statistically significant results of the Phase II trials were disclosed in the publically available SEC filings. Supra at 3; see Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 38 (2011) (defining an omission as material under Section 10(b) when "there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."). The further disclosure of these negative outcomes and unknowns would not have "significantly alter[ed] the total mix of information available to shareholders" because the information was already available to

[7] The alleged omissions are: (1) The second Phase II trial indicated that trabo administered with latan was inferior to timolol administered with latan. See Doc. No. 40-1 at 1. (2) The first Phase II trial indicated trabo's superiority to a placebo only in doses of 200 and 500 mcg. See id.

[8] The alleged omissions are: (1) The effectiveness of QD dosing of the trabo monotherapy had not yet been studied and remained unknown. See id. at 1. (2) An effective dose of trabo had not yet been established. See Doc. Nos. 40 at ¶ 92; 40-1 at 1. (3) The first Phase II trial did not compare trabo to existing therapies and the trabo monotherapy's relative effectiveness was therefore unknown. See id. at 3.

shareholders in the trial results disclosed in Inotek's SEC filings. The omissions are therefore not material.

4. *Statements concerning QD trabo's relative performance*

Gniadek alleges that Inotek, on several occasions, stated that trabo has beneficial effects "in line with existing therapies" and that this statement is false and misleading because the second Phase II trial demonstrated that trabo was inferior to timolol. See Doc. No. 40-1 at 5. Inotek's statement was not misleading or false at the time that the statement was made. Inotek disclosed the results from the second Phase II trial, which showed that trabo was inferior to timolol. See, e.g., Doc. No. 44-1 at 21 ("[T]he IOP drop at the end of 8 weeks of treatment . . . was less than timolol BID") (emphasis added). Inotek also disclosed the basis for its view that trabo had beneficial effects "in line with existing therapies." In each Form 10-K in which Inotek described the effects of trabo as "in line with existing therapies," Inotek included a chart showing the effects of "existing glaucoma treatments." See Doc. No. 44-6 at 4-5. "The Summary of Existing Glaucoma Treatments" chart indicates that existing treatments had intraocular pressure ("IOP") reduction ranges of 2-8 mmHg. See Doc. No. 44-6 at 4-5. In the first Phase II trial, trabo, when dosed at 500 mcg, "lowered IOP by an average of 4.0 to 7.0 mmHg"—indicating beneficial effects "in line with existing therapies." See Doc. No. 44-6 at 6. Shareholders had available to them the chart comparing IOP reduction ranges of various treatments and the statistically significant results of the Phase II clinical trials (including the results that indicated trabo was inferior to timolol). From this information, shareholders were free to draw their own conclusions about trabo's relative effectiveness.

5. *Statements concerning QD dosing convenience*

Gniadek further alleges that Inotek issued several statements concerning trabo's ability to dose QD and that these statements were misleading because no clinical trial had yet studied the

effectiveness of QD dosing of the trabo monotherapy. See, e.g., Doc. Nos. 40 at ¶ 7; 32 at 44, 45-47. Several of the alleged statements describe trabo's "potential" to dose QD. E.g. Doc. Nos. 32 at 2, 4; 40 at ¶¶ 101, 105-06. These statements were not false or misleading as of the time that the statements were made; they are not affirmative representations about what trabo had been shown to do but rather statements about what it *might* be shown to do going forward. Cf. In re Peritus Software Servs., Inc. Sec. Litig., 52 F. Supp. 2d 211, 227 (D. Mass. 1999) ("The securities laws mandate disclosure—not clairvoyance."). Inotek disclosed the basis for its view that trabo had the potential for QD dosing: "After 28 days of BID dosing, the [positive effects of trabo] persisted for an additional 24 hours after the last dose of medication, which we believe indicates the potential for *trabodenoson* monotherapy to be dosed QD." Doc. No. 44-1 at 17. Furthermore, Inotek disclosed that there may be differences in the effects of a single dosage of the trabo monotherapy from a single dosage of trabo administered with latan. See Doc. No. 44-1 at 6. Finally, Gniadek has not alleged that Inotek, at any time, issued a statement to the effect that the Phase II trials studied the trabo monotherapy dosed QD. Accordingly, Inotek's statements as to trabo's potential for QD dosing were not misleading.

Gniadek has also alleged that, at various times during the class period, Inotek issued statements describing trabo's "ability to dose QD or BID" and describing trabo as having "convenient dosing." See, e.g., Doc. Nos. 31 at 45, 47; 40 at ¶ 101. These statements are not statements about trabo's potential but trabo's ability; from these statements, a shareholder might form the false impression that clinical trials had demonstrated trabo's effectiveness when administered QD. At the time that these statements were made, Inotek had conducted studies of QD dosing of trabo with latan but no studies in which trabo, on its own, was dosed QD. Doc. No. 40 at ¶ 7. Gniadek has therefore perhaps plausibly alleged a misrepresentation. Any such

misrepresentation, however, was not "material" because Inotek disclosed the results and methods of its Phase II clinical trials. See Doc. No. 44-1 at 12-25. From these disclosures, shareholders had the information that trabo's effectiveness when administered QD had not yet been demonstrated by a clinical study. Cf. Basic Inc. v. Levinson, 485 U.S. 224, 262, 108 S. Ct. 978, 999, 99 L. Ed. 2d 194 (1988) (accepting the premise that "market professionals generally consider most publicly announced material statements about companies.").

Gniadek's failure to allege any materially false or misleading statements or omissions thus provides an independent ground for the Court's dismissal of Gniadek's Section 10(b)/Rule 10b-5 Claims.

B. Section 20(a) Claims

Count II of the Complaint alleges violations of Section 20(a) of the Exchange Act ("Section 20(a)"), 15 U.S.C. § 78t. Doc. No. 40 at ¶¶ 163-167. Section 20(a) provides that "[e]very person who, directly or indirectly, controls any persons liable under [the Exchange Act] shall also be liable jointly and severally" unless "the controlling person acted in good faith." Id. at § 78t(a). Liability under Section 20(a) requires a "primary violation." Aldridge v. A.T. Cross Corp., 284 F.3d 72, 84 (1st Cir. 2002). Gniadek has failed to sufficiently allege a primary violation. See supra. For this reason, the Court ALLOWS Inotek's motion to dismiss as to Count

III. CONCLUSION

For the foregoing reasons, the Court ALLOWS Inotek's motion to dismiss.[9] Doc. No. 42.

SO ORDERED.

/s/ Leo T. Sorokin
Leo T. Sorokin
United States District Judge

[9] In a one sentence footnote at the end of the Gniadek's memorandum in opposition to dismissal, Doc. No. 46, Gniadek requests leave to amend"[i]f the Court finds any deficiencies in the SAC [the Complaint]." This request is DENIED. It fails to conform to Rule 15. Moreover, this case has been pending since January 6, 2017. Gniadek has filed in total three complaints, Docket numbers 1, 32 and 40, the last of which was filed approximately nine months after the initial complaint and approximately nine months ago. Nothing before the Court nor within Gniadek's request suggests that an opportunity for the filing of a fourth complaint will result in a viable pleading.