UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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| IN RE ALKERMES PUBLIC LIMITED COMPANY SECURITIES LITIGATION | **MEMORANDUM AND ORDER** 18-CV-7410 (LDH) (RML) |

LASHANN DEARCY HALL, United States District Judge:

Lead Plaintiff Midwest Operating Engineers Pension Trust Fund, individually and on behalf of all other similarly situated individuals, brings the instant putative class action against Defendants Richard F. Pops, James M. Frates, Elliot Ehrich, and Blair C. Jackson (collectively, the "Individual Defendants"); and Alkermes Public Limited Company ("Alkermes") (together with the Individual Defendants, "Defendants") asserting claims for violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). Defendants move pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure to dismiss the complaint in its entirety.

## BACKGROUND[1]

### I. Regulatory Framework for the Approval of a New Drug

Under the Federal Food, Drug, and Cosmetic Act, the FDA is tasked with ensuring that drugs and devices are safe and effective for their intended uses. 21 U.S.C. §§ 351–360. Companies seeking to commence a clinical investigation of a new drug must submit an Investigational New Drug Application ("IND") to the FDA. 21 C.F.R. § 312.20. A clinical investigation is generally divided into three phases. *See* 21 C.F.R. § 312.21. Phase 1 includes the initial introduction of the drug into humans, and generally involves 20 to 80 patients. 21 C.F.R. § 312.21(a). Phase 2 includes controlled clinical studies conducted to evaluate the

[1] The following facts are taken from the amended complaint and are assumed to be true for the purpose of this memorandum and order, unless otherwise indicated.

effectiveness of the drug for a particular indication in patients with the disease or condition under study and generally involves no more than several hundred subjects. 21 C.F.R. § 312.21(b). Phase 3 includes expanded controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and usually includes several hundred to several thousand subjects. 21 C.F.R. § 312.21(c).

After the three clinical trial phases are complete, but prior to filing a New Drug Application ("NDA"), a sponsoring company meets with the FDA to exchange information about the proposed drug marketing application. 21 C.F.R. § 312.47(2). This pre-NDA meeting provides an opportunity for the sponsoring company to: [1] "uncover any major unresolved problems," [2] "identify those studies that the sponsor is relying on as adequate and well-controlled to establish the drug's effectiveness," [3]" identify the status of ongoing or needed studies adequate to assess pediatric safety and effectiveness," [4] "acquaint FDA reviewers with the general information to be submitted in the marketing application (including technical information)," [5] "discuss appropriate methods for statistical analysis of the data," and [6] "discuss the best approach to the presentation and formatting of data in the marketing application." 21 C.F.R. § 312.47(b)(2).

Once a pre-NDA meeting is had, the sponsoring company may then formally request FDA approval of a drug for marketing in the United States through submission of an NDA. 21 C.F.R. § 314.50. The NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured. *Id*. The FDA has 60 days after an NDA is received to decide whether to file the NDA for review. 21 C.F.R. § 314.101(a). If the FDA determines that the filing of the NDA should be refused, the FDA will notify the applicant in writing (the "RTF letter") and state the reason for the refusal.

21 C.F.R. § 314.101(a)(3). At such time, the applicant is provided an opportunity to amend its application and resubmit it to the FDA for review. *Id.* Where the FDA finds no basis to refuse the filing of an NDA, the FDA will file the NDA for substantive review. 21 C.F.R. § 314.101(a), (a)(2). Once the review is complete, the FDA will either approve the NDA or issue a complete response letter rejecting the application. 21 C.F.R. § 314.110(a). Approvals are not granted, however, until after the FDA "determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling[.]" 21 C.F.R. § 314.105(a), (c).

## II. Alkermes's Development of ALKS 5461

Alkermes is a global biopharmaceutical company that uses scientific expertise and proprietary technologies to "research, develop, and commercialize pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas." (Compl. ¶¶ 19, 28 (internal modification omitted).) At some point prior to February 2011, Alkermes began developing ALKS 5461, an opioid combination product originally intended to treat Major Depressive Disorder ("MDD") and cocaine dependence. (*Id.* ¶¶ 2, 34.) Had it been approved, ALKS 5461 would have been the first drug in a new class to treat MDD. (*Id.* ¶ 2.) On February 17, 2011, Alkermes participated in a pre-IND meeting with the FDA concerning the development of ALKS 5461. (*Id.* ¶ 34.) During that meeting, Alkermes described its plan for an 8-week safety and tolerability study and disclosed its plan to use a Sequential Parallel Comparison Design ("SPCD") testing method. (FDA Brief 8, ECF No. 49-6 .)[2] "The [FDA] voiced no objection to a SPCD proof-of-concept study, but strongly encouraged [Alkermes] to provide a detailed statistical analysis plan and seek feedback prior to initiating the trial if they

[2] The FDA Briefing Document referenced herein was not attached, but is incorporated by reference to the complaint. *Kramer v. Time Warner Inc*., 937 F.2d 767, 773 (2d Cir. 1991) ("[A] district court must limit itself to facts stated in the complaint or in documents attached to the complaint as exhibits or incorporated in the complaint by reference.")

intended to use the study to support an efficacy claim." (*Id*. 9.) Alkermes clarified, however, that the SPCD study "was intended to be used as a proof-of-concept study, not to establish efficacy." (*Id*. 9.)

On April 8, 2011, Alkermes filed an IND with the FDA for the use of ALKS 5461 for the treatment of MDD. (Compl. ¶ 36.) A subsequent IND was filed on June 11, 2011, this time limited to cocaine dependence. (*Id*. ¶ 35.) Then, in January 2012, Alkermes announced positive results from a "Phase 1/Phase 2 study," of ALKS 5461 in 32 patients with MDD. (*Id*. ¶ 36.) Based on that study, Alkermes reported that ALKS 5461 significantly reduced depressive symptoms and was generally well tolerated. (*Id*. ¶ 36.) The company then initiated a Phase 2 study, the results of which were expected in the first half of 2013. (*Id*. ¶ 37.) This study was a randomized, double-blind, multicenter, placebo-controlled study designed "to evaluate the efficacy and safety of ALKS 5461 when administered once daily for four weeks in approximately 130 patients with MDD who ha[d] inadequate response to antidepressant therapy." (*Id*.) Upon completion of Phase 2, in April 2013, Alkermes announced that the study had positive results, in that the drug demonstrated reduced depressive symptoms across a range of standard measures and was generally well-tolerated. (*Id*. ¶ 38.) At that time, Alkermes also announced its intention to request a meeting with the FDA and to "advance ALKS 5461 into a pivotal development program." (*Id*.) Sometime in late April 2013 Alkermes abandoned its intention to use ALKS 5461 to treat cocaine dependence. (*Id*. ¶ 39.)

In October 2013, Alkermes announced that it had successfully completed its End-of-Phase 2 interactions with the FDA. (*Id*. ¶ 40.) Alkermes also announced that the FDA had

granted ALKS 5461 "Fast Track"[3] status for the adjunctive treatment of MDD in patients with an inadequate response to standard therapies. (*Id*. ¶ 40.) It was expected that the Phase 3 study would commence in the first quarter of 2014, with approximately 1,500 patients expected to enroll. (*Id*. ¶ 40.) Alkermes represented that "[t]he primary efficacy endpoint for all phase 3 studies w[ould] be the change in Montgomery-Åsberg Depression Rating Scale ("MADRS") scores from baseline"; and that Phase 3 would "evaluate remission as a secondary endpoint" and "include studies to evaluate the long-term safety, pharmacokinetic profile, titration schedule and human abuse liability of ALKS 5461." (*Id*.)

Sometime in late 2013, Alkermes requested an End of Phase 2 meeting with FDA and provided the agency with a related background package. (*Id*. ¶ 41.) Therein, Alkermes described its plan to conduct three Phase 3 confirmatory efficacy studies (ALK5461-205, ALK5461-206, and ALK5461-207) and one long-term safety study (ALK5461-208). (FDA Brief 9.) Alkermes also indicated that it intended change from baseline in total MARDS score as the primary endpoint in all three of the planned Phase 3 studies. (*Id*.) In turn, the FDA provided Alkermes written responses, which expressed its concerns about the planned SPCD analysis. (*Id*.) Specifically, the FDA stated:

> From a statistical perspective, although the proposed SPCD appears to be reasonable, there has been no analytical proof for the validity of associated statistical analyses when there are missing data. In the cited Chen et al. paper, the type I error rates were estimated by simulation. Without theoretical proof, it is not guaranteed that the type I error rate will be controlled, especially in scenarios where there are extensive dropouts. Since statistical validity of the methods associated with this novel design is not yet clear when there are missing data, it will be a matter of review whether or not efficacy demonstration can primarily rely on this method. We note that you have pre-specified the MMRM approach as outlined by Chen et al. as the primary analysis and a few sensitivity analyses. To further assess the impact of missing data, you should propose sensitivity analyses that do not require

[3] Fast Track is "a process to facilitate the development and expedite the review of drugs to treat serious conditions with the potential to address an unmet medical need." Fast Track, FDA (Jan. 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

> the MAR (missing at random) assumption and provide details in the Statistical Analysis Plan.

(*Id*. 9-10; Compl. ¶ 65.) Upon receiving the FDA's responses, Alkermes withdrew its meeting request and informed the FDA that its written responses addressed the company's questions. (Compl. ¶ 41.) Subsequently, Alkermes submitted the results of its three Phase 3 protocols, and the long-term safety protocol to the FDA. (FDA Brief 10.) Following Alkermes's submission, the FDA advised the company to monitor for certain effects of the drugs, and refine the time points for administration. (*Id*.)

On May 12, 2015, Alkermes requested a meeting with the FDA in an effort to reach agreement on the Statistical Analysis Plans for Phase 3 studies ALK5461-205 and ALK5461-206. (Compl. ¶ 44.) On July 24, 2015, the FDA provided a written response to Alkermes's meeting request and indicated that:

> We would like to reiterate that we haven't endorsed any analytical method for SPCD in a confirmatory trial setting. We are continuing making efforts in further understanding its pros and cons from a regulatory perspective. You are encouraged to collect efficacy data from both stages. However, we may determine the efficacy based on data from only Stage 1 if analysis associated with this novel design is still unsettled by the time of your NDA filing. Because of the limited time available for review of submissions via a meeting category, we can only provide general guidance on the proposed questions. If there is any change in protocol or stand-alone SAP, we advise that you submit it (including tracked changes and/or a detailed list of changes) separately from a meeting package.

(*Id*. ¶ 44; FDA Brief 10.)

On September 19, 2016, Alkermes submitted an amendment to the statistical analysis plan and protocol for an upcoming study. (Compl. ¶ 67.) The amendment "changed the primary efficacy endpoint from baseline to end-of-treatment on the MADRS-10 to three primary endpoints to be evaluated in a hierarchical fashion" as follows:

- Change in MADRS-6 using average of changes from baseline to Week 3 through the end of efficacy period (Week 5 for Stage 1; Week 6 for Stage 2)

- Change in MADRS-10 score using average of changes from baseline to Week 3 through the end of efficacy period (Week 5 for Stage 1; Week 6 for Stage 2)
- Change in MADRS-10 score from baseline to end of treatment (Week 5 for Stage 1; Week 6 for Stage 2)

(FDA Brief 10-11.)

Subsequently, on September 26, 2016, Alkermes met with the FDA to share preliminary results from studies it had conducted in connection with Phase 3. (*Id*. 10.) During that meeting, Alkermes "acknowledged that neither study met its prespecified primary endpoint and inquired about any additional analyses that could be conducted." (*Id*.) The FDA "had no recommendations but acknowledged that the additional analyses [that Alkermes had] already conducted could be informative for subsequent studies." (*Id* 10.)

Because the September 19, 2016 amendments to the statistical analysis plan were submitted just 7 days prior to the September 26 meeting, the FDA was unable to review the amendments in advance and discussion on the amendments was tabled until a February 13, 2017, guidance meeting. (*Id*. 10-11.) In advance of the February 13 meeting, the FDA provided the following comments relative to the efficacy analyses to Alkermes:

1. In general, we do not accept major changes, such as revising the primary efficacy measures, in the late stage of a clinical trial. It appears that the primary endpoint and duration of the efficacy period for Stage 2 were changed very late in the course of the study.

2. We have not previously accepted the MADRS-6 as a primary efficacy endpoint for a clinical trial. Before accepting this instrument as primary endpoint in a trial intended to support product registration, we would need data on the validity and reliability of the instrument, and clear documentation of how the biometric properties of the MADRS-6 compare to the MADRS-10. On face, we have concerns that the MADRS-6 omits diagnostically and clinically important aspects of depression.

3. We do not agree with the strategy of comparing the baseline MADRS-6 or MADRS-10 scores to the average of the scores from Week 3 to the end of the efficacy period. We note that the averaging of the change in MADRS-6 or MADRS-10 scores tends to obscure a possible drop[-]off in drug efficacy after the first few weeks of treatment.

In Study 205, the change in MADRS-10 scores reached a peak at Week 3. In Study 207, the change in MADRS-6 and MADRS-10 scores both reached a peak at Week 4. It is important for us to know whether the drug has an effect that persists until the end of the study. We recommend using a single efficacy measure at the end of the study, and not an average over multiple time periods, as the primary efficacy endpoint.

4. With the protocol amendment for Study 207, the efficacy period in Stage 1 is now different in duration from the efficacy period in Stage 2. This adds some complexity to the comparison of data from the two SPCD stages. Please provide a rationale for the difference in duration of the efficacy periods.

(*Id*. 11.) The FDA also noted that "although the SPCD study design limits the conclusions that can be drawn with respect to drug efficacy when treatment response is compared across stages, the analysis did help to reduce the Division's concern about a possible loss of drug efficacy after Week 4;" and recommended that the Applicant submit a dossier for the MADRS-6, including reliability, validity, scoring instructions, rationale for item selection, and justification for its use in antidepressant efficacy trials. (*Id*. 12.)

On March 3, 2017, Alkermes submitted a preliminary Breakthrough Therapy Designation Request to the FDA. (Compl. ¶ 51.) Where granted, the designation allows for the "expedited development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint." (Compl. ¶ 51.) The FDA informed Alkermes that "because [it] had not yet determined whether the MADRS-6 was an acceptable endpoint, and because any statistical significance in the Phase 3 study results depended on *post hoc* analyses, it would be difficult for [the FDA] to grant Breakthrough Therapy Designation." (FDA Brief 12.)

On April 24, 2017, Alkermes submitted the dossier on the MADRS-6 previously requested by the FDA. (*Id*.) The FDA's clinical outcomes assessment staff evaluated the submission, and concluded that, consistent with the FDA's original thinking, "MADRS-6 could not replace the MADRS-10 for use as a primary endpoint because it excludes concepts that are

relevant [to] and important in [major depressive disorder]." (*Id*.) The FDA informed Alkermes of the clinical outcomes assessment staff's conclusions during a July 24, 2017 pre-NDA meeting, and informed Alkermes "that any analyses of MADRS-6 scores would be considered exploratory." (*Id*.)

On January 31, 2018, Alkermes submitted the final portion of the NDA for ALKS 5461. (*Id*.) The FDA "initially refused to file the application," but ultimately agreed to review the NDA, after Alkermes "clarified the analyses intended to support [its] efficacy claim." (*Id*.) On April 2, 2018, Alkermes announced it has received an RTF letter from the FDA regarding its NDA for ALKS 5461. (Compl. ¶ 59.) The announcement indicated:

> [T]he FDA has taken the position that it is unable to complete a substantive review of the regulatory package, based on insufficient evidence of overall effectiveness for the proposed indication, and that additional well-controlled clinical trials are needed prior to the resubmission of the NDA for ALKS 5461. In addition, the FDA has requested the conduct of a bioavailability study to generate additional bridging data between ALKS 5461 and the reference listed drug, buprenorphine.

(*Id*.) Following, on October 30, 2018, the FDA released the Briefing Document regarding ALKS 5461's NDA. (*Id*. ¶ 63.) On November 1, 2018, the FDA Advisory Committees voted against the approval of ALKS 5461. (*Id*. ¶ 71.)

**III. Alkermes's Leadership Team**

At all times relevant to the instant action: Pops served as Alkermes's Chairman of the Board of Directors and Chief Executive Officer; Frates served Alkermes's Chief Financial Officer; and Jackson served as the Senior Vice President of Corporate Planning. (*Id*. ¶¶ 20–21, 23.) Ehrich served as Alkermes' Chief Medical Officer and Executive Vice President of Research and Development from September 2011 to May 2017 and Alkermes' Executive Vice President of Research and Development from May 2017 until January 2018. (*Id*. ¶ 22.) In their capacities as CEO and CFO, respectively, Pops and Frates were responsible for signing all of

Alkermes's 10-K and 10-Q forms during the during the period from July 31, 2014 through and including November 1, 2018 (the "Class Period"), and making statements on behalf of the company in press releases, in conferences, and on business calls with analysts. (*Id*. ¶¶ 20–21.) As Chief Medical Officer, Ehrich attended meetings with the FDA on behalf of Alkermes and made statements at industry conferences and conferences with analysts. (*Id*. ¶ 22.) Jackson also made statements on behalf of the company at conferences with analysts. (*Id*. ¶ 23.) According to the amended complaint, the Individual Defendants "had access to adverse undisclosed information about [Alkermes'] business, operations, finances, and present, and future business prospects via access to internal corporate documents; conversations and connections with other corporate officers and employees; attendance at management, sales and/or Board of Directors meetings and committees;" and "via reports and other information provided to them." (*Id*. ¶ 24.)

**STANDARD OF REVIEW**

Generally, to withstand a Rule 12(b)(6) 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.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the alleged facts allow the court to draw a "reasonable inference" of a defendant's liability for the alleged misconduct. *Id*. With respect to claims alleging fraud, however, Rule 9(b) requires plaintiffs to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).

In addition to the requirements of Rule 9(b), a plaintiff seeking to avoid dismissal of a securities complaint must also satisfy the pleading requirements included in the Private Securities Litigation Reform Act ("PSLRA"). *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 110 (2d Cir. 2009). Congress enacted the PSLRA in 1995 in part "[a]s a check against

abusive litigation by private parties." *Id*. at 111. To accomplish this goal, Section 21D(b)(2) of the PSLRA, codified at 15 U.S.C. § 78u–4(b)(2), provides that:

> [i]n any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

*Id*.

## DISCUSSION

### I. Exchange Act Section 10(b) and Rule 10b-5

"To state a claim on which relief can be granted under § 10(b) and Rule 10b–5, a plaintiff must plead, inter alia, that in connection with the purchase or sale of securities, the defendant made a false representation as to a material fact, or omitted material information, and acted with scienter." *S. Cherry St., LLC*, 573 F.3d 9 at 108. Defendants contend that Plaintiff's claim is ripe for dismissal on a number of grounds, including Plaintiff's failure to sufficiently allege that Defendants made any material misstatement or omission, acted with scienter, or caused any loss that Plaintiff suffered. (Mem. L. Supp. Defs.' Mot. Dismiss ("Defs.' Mem.") 16–30, ECF No. 48.) That said, Defendants also maintain that the Court need not resolve each of these issues as the lack of scienter alone justifies dismissal. (*Id*. 16.) The Court agrees.

"The Supreme Court has defined scienter as 'a mental state embracing intent to deceive, manipulate, or defraud.'" *S. Cherry St., LLC*, 573 F.3d at 109 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007)). A plaintiff sufficiently pleads scienter by alleging facts that demonstrate that a defendant had motive and opportunity to commit fraud, or a strong showing of reckless disregard for the truth. *ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co*., 553 F.3d 187, 198 (2d Cir. 2009). In this case, Plaintiff has

effectively conceded that the complaint is devoid of allegations of motive or opportunity. Instead, the Plaintiff reminds the Court that "the absence of a motive allegation is not fatal." (Pl.'s Opp'n 18.) Of course, this is true. It is also true, as Defendants note, that in the absence of allegations going to motive or opportunity, allegations of recklessness "must be correspondingly greater." *ECA*, 553 F.3d at 198-99.

Recklessness in this context means "a state of mind approximating actual intent, and not merely a heightened form of negligence." *S. Cherry St., LLC*, 573 F.3d at 109. To constitute recklessness, the conduct must be "at the least . . . highly unreasonable and . . . represent[] an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it . . . . " *Id.* (internal quotations and citations omitted). Courts in this circuit have had many occasions to address the issue of scienter premised on recklessness in cases involving the development of a new drug. *See Lehmann v. Ohr Pharm. Inc.*, No. 18 CIV. 1284 (LAP), 2019 WL 4572765, at *4 (S.D.N.Y. Sept. 20, 2019) (collecting cases), *aff'd and remanded*, 830 F. App'x 349 (2d Cir. 2020). Those cases have explored the circumstances under which the public dissemination of information in the course of a drug approval process constitutes securities fraud. Through the collective wisdom of those cases, this Court is advised that "the law [does] not impose an affirmative duty to disclose the FDAs interim feedback just because it would be of interest to investors." *In re Sanofi Sec. Litig.*, 87 F. Supp 3d 510, 534 (S.D.N.Y. 2015), *aff'd*, *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *see also id*, 816 F.3d at 212 ("Defendants need not have disclosed the FDA feedback merely because it tended to cut against their projections—Plaintiffs were not entitled to so much information . . . . "). That is, "the mere allegation that defendants failed to disclose relevant information does not in and of itself constitute strong evidence that

they did so with scienter." *In re Sanofi Sec. Litig.*, 87 F. Supp 3d at 534 (internal modification omitted) (citing *Fort Worth Employers' Ret. Fund v. Biovail Corp*., 615 F. Supp. 2d 218, 226 (S.D.N.Y. 2009)) Indeed, there is no scienter if a company releases positive reports about a drug which it genuinely believes to be true. *Id*. Scienter arises in this context, where "the management knows that certain facts will necessarily prevent regulatory approval . . . and conceals those facts from the investing public." *Id* at 529.[4]

Plaintiff argues that the Individual Defendants' "roles at Alkermes alongside the fact that ALKS 5461 was a 'blockbuster' drug in which the Company had invested significant resources bolster an inference that the Individual Defendants either knew or recklessly disregarded the concerns the FDA conveyed to the Company during the Class Period." (Pl.'s Opp'n 23.) Plaintiff further argues that Defendants' contention that these highly placed executives were unaware of the concerns conveyed by the FDA strains credulity. (*Id*. 19.) Plaintiff misapprehend Defendants argument on this point. Defendants argument here is that Plaintiff has failed to include particularized allegations on a Defendant-by-Defendant basis. (Defs.' Mem. 22-23.) In opposition, Plaintiff points to public statements made by the Individual Defendants, which they maintain evinces the Individual Defendants knowledge of the discussions between Alkermes the FDA regarding progression of the ALKS 5461 drug trial. (Pl.'s Opp'n 20.) Perhaps. However, Plaintiff's argument only serves to establish scienter if the court finds that

[4] Plaintiff takes issue with this articulation of the standard arguing that it is "nonsensical." (Pls. Mem. L. Opp'n Defs.' Mot. Dismiss ("Pls.' Opp'n") 26, ECF No. 50.) According to Plaintiff such a standard would allow a Defendant who is "aware with 99% certainty that a drug will be rejected" would be "free to tout it to the market because the facts at the time do not 'necessarily prevent' approval." (*Id*.) Plaintiff is clearly prone to hyperbole and the Court does not view the standard so expansively. In any event, as argued by Plaintiff, according to the Supreme Court in *Tellabs*, scienter is alleged if after a holistic analysis of plaintiff's allegations, "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." (*Id*. 18 (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd*., 551 U.S. 308, 324 (2007).) The Court does not deem this proposition of law as at odds with Defendant's position. But lest there be any doubt, as set forth in detail below, even after undertaking a holistic analysis the claims cannot survive Defendants motion.

the information conveyed by the FDA was such that it demonstrates that Defendants did not honestly believe that their statements of optimism to the investing public were true. The Court cannot make such a finding.

As a threshold matter, Plaintiff has overstated the import of the information – the "concerns" – conveyed by the FDA to Defendants. Indeed, the Court is troubled by Plaintiff's blatant mischaracterization of the November 2018 FDA briefing document, upon which they rely exclusively to support their argument for scienter. For example, Plaintiff asserts in opposition that at the February 17, 2011[5] meeting the "FDA had told Alkermes the SPCD could not be used for proof of efficacy and Alkermes used it anyway." (Pls. Opp'n. 26.) The FDA made no such declaration. Instead, according to the FDA Briefing Document, the FDA "voiced no objection to a SPCD in a proof-of-concept study, but strongly encouraged [Alkermes] to provide a detailed statistical analysis plan (SAP) and seek feedback prior to initiating the trial if they intended to use the study to support an efficacy claim." (FDA Brief 9.) Likewise, Plaintiff's unsupported assertion that Alkermes was told "with certainty, that the design of its clinical trials would necessarily prevent approval" borders on pure fantasy. (Pl.'s Opp'n 22) No such language appears in the FDA briefing document.

Nonetheless, Plaintiff maintains that the FDA Briefing Document is "a roadmap to Defendants' scienter," which includes "at least seven different interactions with the FDA during the Class Period in which Defendants became aware of the FDA's concerns about the statistical protocol [Alkermes] was using for ALKS 5461." (Pls.' Opp'n 19.) However, a review of the FDA Briefing Document, does not reveal any information conveyed to Alkermes that should reasonably have been interpreted to suggest that FDA approval of ALKS 5461 was not possible

[5] In making this argument, Plaintiff does not indicate the date on which this representation was made, however, Plaintiff cites to Paragraph 64(b) of the complaint, which relates to the February 17, 2011 meeting.

or even unlikely. Rather, implicit in the ongoing dialogue between the FDA and Alkermes was a collective expectation that the process was an iterative one and that Alkermes would continue to respond to feedback in its continued effort to seek approval of ALKS 5461. Indeed, contrary to Plaintiff's suggestions, the FDA did not take a dim view of Alkermes's proposed trial methods at the outset. In the introductory remarks to the FDA Brief, the agency highlighted that the use of SPCD, while novel, should be "discussed." (FDA Brief 5.) The FDA further indicated that Alkermes's use of an averaging approach to establish an endpoint "seem[ed] worthy of consideration." (*Id*.) This general sentiment pervaded the FDA's discussions with Alkermes.

As noted by Defendants, at the February 2001 pre-IND meeting, the FDA "voiced no objection to the use of SPCD as a proof-of-concept study." (FDA Brief 9.) And to the extent Alkermes intended to rely on SPCD to establish ALKS 5461's efficacy, the FDA stated only that it "strongly encouraged [Alkermes] to provide a detailed statistical analysis plan . . . and seek feedback prior to initiating the trial." (FDA Brief 9.) This can hardly be said to constitute an outright rejection of SPCD or an indication that one was forthcoming. In the FDA's October 2013 written responses, it indicated that SPCD "appear[ed] . . . reasonable." (FDA Brief 9.) While the FDA also noted that the "statistical validity of the methods associated with this novel design is not yet clear," this observation did not result in the rejection of SPCD. (FDA Brief 10.) Instead, the FDA indicated only that "it will be a matter of review whether or not efficacy demonstration can primarily rely on this method." (*Id*.) The FDA then granted ALKS 5461 Fast Track status for the treatment of MDD in certain patients. (Compl. ¶ 40.) In written responses to Alkermes in July 2014, although the FDA advised Alkermes that it had not "endorsed any analytical method for SPCD in a confirmatory trial setting" it also advised that it was "continuing making efforts in further understanding of its pros and cons from a regulatory

perspective." (*Id*.) Contrary to Plaintiff's urging, this is not a "clear disapproval" of SPCD. (*Id*. ¶ 45.) And, when Alkermes relayed in September 2016 that two studies failed to meet the company's primary endpoint and inquired about potential additional analysis, the FDA had no recommendation and "acknowledged that the additional analysis [Alkermes] already conducted could be informative for subsequent studies." (FDA Brief 10.) Ultimately, none of the interactions between the FDA and Alkermes support a strong inference of scienter. Despite expressing concerns regarding Alkermes's trial methodology, the FDA nonetheless permitted the drug to proceed through various stages of approval prior to its ultimate denial of the application. (*Id*. 8-12.) Put differently, the "FDA's negative feedback was muted by a series of encouraging regulatory decisions" which allowed the drug to proceed through the approval process prior to the ultimate disapproval. *In re Sanofi*, 87 F. Supp 3d at 545.

On these facts, the Court cannot discern a strong inference of scienter. Indeed, the complaint fails to support even an inference of fraudulent intent that is "cogent and at least as compelling as the opposing inference of nonfraudulent intent." *ECA*, 553 F.3d at 198. Accordingly, Plaintiff's claims under the Exchange Act § 10(b) and Rule 10b-5 are dismissed.[6]

## II. Exchange Act Section 20(a)

Plaintiff fails to oppose Defendants' arguments for dismissal of the Section 20(a) claim. For this reason, the claim is deemed abandoned and therefore dismissed. *See Silverman v. Household Fin. Realty Corp. of N.Y*, 979 F. Supp. 2d 313, 317 (E.D.N.Y. 2013) ("Since Plaintiffs fail to oppose Defendants' arguments that the other eleven (11) claims should be dismissed, the court deems them abandoned and grants Defendants' motion as to those claims.").

[6] Having determined Plaintiff failed to sufficiently alleged Defendants acted with scienter, the Court need not reach the Defendants' argument concerning loss causation or whether Plaintiff has alleged actionable misstatements or omissions under the PLSRA.

Notably, however, even if Plaintiff's claims were not dismissed on these grounds, having found no scienter, any claim under § 20 of the Exchange Act cannot lie. *In re Sanofi*, 87 F. Supp 3d at 527 ("If plaintiffs have not adequately alleged a primary violation, *i.e.*, a viable claim under another provision of the Securities Act or Exchange Act, then the § 20(a) claims must be dismissed.").

## CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss the complaint for failure to state a claim is GRANTED. Plaintiff's complaint is dismissed in its entirety.

SO ORDERED.

Dated: Brooklyn, New York
February 26, 2020

/s/ LDH
LASHANN DEARCY HALL
United States District Judge