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Federal District Court Determines That Pharmaceutical Company Has No Standalone Obligation to Disclose Interim FDA Feedback on Form 483

Last week a federal district court in the Southern District of New York dismissed a putative securities class action lawsuit against Nabriva Therapeutics plc and several of its officers ("Nabriva") alleging that the company had fraudulently misled investors about its prospects for getting FDA approval for its new drug, CONTEPO. The decision is noteworthy because the plaintiff's principal allegations related to the company's receipt of a "Form 483" from the FDA listing several "significant conditions" requiring corrective action that the FDA observed during an interim inspection of the company's manufacturing plant four months prior to its final evaluation of the drug. The district court joined courts from other circuits and determined that "[b]ecause a Form 483 is interim FDA feedback, there is no standalone duty to disclose its existence," although failure to disclose a Form 483 *could* be actionable if disclosure were necessary to render a company's other statements not misleading.

Background

Nabriva is a biopharmaceutical company based in Ireland. During the relevant period, Nabriva submitted two drug products to the FDA for marketing approval, and did not expect to generate any revenue unless one of its products was approved. The company filed a New Drug Application for CONTEPO in October 2018, with a final FDA decision date of April 30, 2019. In December 2018, the FDA inspected the plant where CONTEPO was being manufactured and issued a Form 483 to the company listing at least 10 observations indicating that the plant might not comply with Current Good Manufacturing Practices ("cGMP"), which could interfere with CONTEPO receiving FDA approval.[1] Nabriva did not disclose its receipt of the Form 483, and continued to issue public statements expressing optimism that CONTEPO would receive FDA approval.[2] On April 30, 2019, the FDA issued a Complete Response Letter withholding approval for CONTEPO based substantially on the cGMP issues identified in the Form 483.[3] After the company's share price declined, a shareholder brought a putative class action alleging that several of the

1 *Schaeffer* v. *Nabriva Therapeutics plc, et al*, No. 19 Civ. 4183, slip op. at 5–6 (S.D.N.Y. Apr. 28, 2020).

2 *Id*. at 7–9.

3 *Id*. at 11.

company's public statements in early 2019 were materially false and misleading in light of the issues identified in the Form 483.[4]

The *Nabriva* Decision

The court first considered whether the receipt and contents of a Form 483 are "material" within the meaning of federal securities law. In a matter of first impression in the Second Circuit, Judge Victor Marrero followed the reasoning of the First and Eighth Circuits and determined that a Form 483 is not *per se* immaterial, although its materiality depends on the facts of any specific case.[5] The court ruled that the Form 483 in this case could be material to an investor, particularly because CONTEPO was one of only two drugs being developed by Nabriva and represented a substantial share of the company's potential revenues.[6]

Second, the court noted that a Form 483 only describes the FDA's "inspectional observations" and does not represent "a final agency determination." Accordingly, the court held that "[b]ecause a Form 483 is interim FDA feedback, there is no standalone duty to disclose its existence."[7]

Finally, the court reviewed each of the alleged misstatements to determine whether any were rendered misleading by the issuance or contents of the Form 483. Several statements were dismissed as inactionable puffery, and several others were found to be protected by the PSLRA's safe harbor, including statements expressing optimism that CONTEPO would receive FDA approval.[8] The court also rejected plaintiff's argument that several statements in Nabriva's 10-K were misleading because they presented the risk of delayed FDA approval as a possibility, rather than a certainty in light of the Form 483's observations. Judge Marrero acknowledged that the FDA's interim observations were "concerning" and "quite serious," but determined that plaintiff failed to allege facts showing why these violations could not be remedied before the final approval date.[9] Lastly, the court found that two of the company's statements—about the potential receipt of FDA "warning letter[s]" and potential FDA "review issue[s]"—could arguably be rendered misleading by the Form 483, but that plaintiff failed to allege a strong inference of fraudulent intent with

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4 *Id*. at 7.

5 *See Pub. Pension Fund Grp*. v. *KV Pharm. Co*., 679 F.3d 972, 982–83 (8th Cir. 2012); *In re Genzyme Corp. Sec. Litig*., 754 F. 3d 31, 42 n.4 (1st Cir. 2014).

6 *Id*. at 26.

7 *Id*. at 27.

8 *Id*. at 27–31.

9 *Id*. at 31–33.

respect to either statement.[10] The court dismissed the complaint and ordered the plaintiff to show cause why the dismissal should not be with prejudice.

Implications of the *Nabriva* Decision

The *Nabriva* decision appears to be the first issued in the Second Circuit providing guidance to pharmaceutical companies about their disclosure obligations with respect to the receipt or contents of a Form 483. First and foremost, the decision provides that there is no standalone duty to disclose a Form 483 to investors. Although such a duty could arise if necessary to correct a prior statement, the contents of a Form 483—even if "concerning"—do not render misleading forward-looking statements expressing optimism about FDA approval. Similarly, unless the significant conditions identified in a Form 483 are so dire that they cannot be remedied before a scheduled FDA approval date, it does not render misleading statements portraying the risk of delayed approval as a mere possibility rather than a certainty. Finally, although the court found that the Form 483 in this case was not immaterial as a matter of law, it left open the possibility that the receipt and contents of such a form could be immaterial to a company that is less dependent on the approval and success of a particular drug.

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[10] *Id*. at 34–36, 38.

This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

Susanna M. Buergel
+1-212-373-3553
sbuergel@paulweiss.com

Andrew J. Ehrlich
+1-212-373-3166
aehrlich@paulweiss.com

Daniel J. Kramer
+1-212-373-3020
dkramer@paulweiss.com

Audra J. Soloway
+1-212-373-3289
asoloway@paulweiss.com

Associate Mariah Rivera and Securities Litigation & Enforcement Practice Management Associate Daniel Sinnreich contributed to this client memorandum.