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Life Sciences Company Hit with $4 Million SEC Penalty

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On March 29, the US Securities and Exchange Commission announced that AVEO Pharmaceuticals, Inc., a Massachusetts-based pharmaceutical company, agreed to pay a $4 million penalty to settle fraud charges that it failed to disclose a US Food and Drug Administration recommendation that the Company conduct a second clinical trial of for its flagship kidney cancer drug, Tivozanib, as part of the drug approval process. (*SEC v. AVEO Pharmaceuticals, Inc., et al*, Case No. 16-CV-10607 (D. Mass Mar. 29, 2016).) The SEC alleged that despite the fact that AVEO disclosed that the FDA had concerns about the death rate for Tivozanib in its August 2, 2012 press release and August 7, 2012 quarterly report on Form 10-Q, AVEO's statements were false and misleading because it failed to disclose that the FDA had recommended that the Company conduct a second clinical trial to address these safety concerns.

In announcing the settlement, Paul G. Levenson, Director of the SEC's Boston Regional Office warned: "Companies must be forthcoming about their communications with regulators so investors can make informed investment decisions while knowing what challenges may lay ahead."

This case follows SEC Enforcement Director Andrew Ceresney's speech last year at CBI's Annual Pharmaceutical Compliance Congress where he emphasized that disclosures concerning FDA communications were a focus for the SEC. At that conference, Mr. Ceresney stated, "One significant type of key event that we see causing problems with disclosure in your industry is disclosures on your dealings with the FDA. Accuracy of reporting in your dealings with the FDA is critical to getting investors the information they need."

Though life science companies are no stranger to private shareholder litigation alleging that companies misrepresented the risks associated with their drugs, traditionally, life sciences is not an area where the SEC has been particularly active. In the wake of Mr. Ceresney's speech last March and the *AVEO* case, life science companies and their executives must be cognizant that disclosures related to the regulatory process will likely be scrutinized not just by private litigants but also by the SEC.

Factual background

On May 11, 2012, before it filed a New Drug Application ("NDA"), AVEO met with FDA officials to discuss the results of its Tivozanib clinical trial. During this meeting, the FDA staff expressed concerns about overall survival rates among clinical trial participants. Further, the FDA "recommended that [AVEO] conduct a second adequately powered randomized trial in a population comparable to that in the US."

In its August 2012 press release and quarterly report on Form 10-Q, the Company disclosed the FDA's concern about the overall survival rate, but did not disclose that the FDA recommended AVEO conduct another clinical trial. In addition, during an August 2, 2012 investor call, when specifically asked what the FDA might want with respect to additional studies or analysis, company executives declined to "speculate." The SEC alleged that these statements were misleading because the FDA had, in fact, recommended an additional clinical trial.

On April 30, 2013, in advance of a meeting with an advisory panel of experts convened by the FDA to evaluate AVEO's NDA, the FDA staff released a "pre-meeting summary" that disclosed the FDA's May 2012 recommendation that AVEO conduct an additional clinical trial. That same day, AVEO's stock fell 31%. Approximately one month later, the FDA denied approval of Tivozanib.

The Complaint, filed on March 29, 2016, alleges violations of Section 10(b) and 10b-5 and Section 17(a) against the Company and three of its former officers; Exchange Act Rule 13a-14 violations against the Company's CEO and CFO; and 13(a) of the Exchange Act and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13 violations against the Company.

Partial resolution

The Company has agreed to pay a $4 million penalty to settle the charges without admitting or denying the allegations in the Complaint. The settlement is awaiting court approval. The SEC's case, however, continues against AVEO's former chief executive officer, chief financial officer, and chief medical officer. In addition to disgorgement and civil monetary penalties, the SEC is seeking officer-and-director bars against these three executives.

Implications

Determining whether to disclose an FDA communication (whether via in-person meetings or informal telephone calls or emails) needs to be considered carefully and will continue to be a fact-specific analysis. However, companies should be wary of trying to "spin" or downplay FDA concerns or comments. As *AVEO* makes clear, companies and their officers could face potential liability if they affirmatively misrepresent or omit key facts about their dealings with the FDA. Companies must take care to ensure that any public disclosures accurately reflect the company's communications with the FDA or other regulatory body.

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