August 21, 2019

SEC Charges Life Sciences Company with Regulation FD Violations

On August 20, 2019, the SEC settled charges against TherapeuticsMD, a Florida-based life sciences company, for violating Regulation FD by selectively communicating to sell-side analysts information about meetings with FDA. The company paid a fine of $200,000 but neither admitted nor denied the violations. No individuals were charged.

Background

On May 5, 2017, TherapeuticsMD received from FDA a Complete Response Letter (CRL) relating to a drug for which it had filed a New Drug Application (NDA). TherapeuticsMD had two drug candidates, and this was its first NDA. FDA sends a CRL when it has determined that it will not approve an NDA in its present form. The letter cited a single deficiency - the lack of long-term safety data for the drug candidate. TherapeuticsMD requested and received a meeting date of June 14 to discuss the letter with FDA officials and announced the planned meeting in a Form 8-K, noting that the two likely paths forward were either resubmission of a revised NDA or dispute resolution with FDA.

On June 15, the day following the meeting, the company sent emails to six sell-side analysts. The emails described the FDA meeting as "very positive and productive" and indicated that the company would be waiting for the meeting minutes to decide on a path forward. Some of the emails offered to discuss the matter further, and at least three of the analysts took the company up on its offer. A follow-up email to one analyst indicated that the company was "pleasantly surprised at how accommodating" the FDA officials were.

The following day, June 16, the company's stock price increased significantly (approximately 21%) on heavy volume. The NYSE contacted the company, and the executives with whom they spoke, who were not aware of the emails sent the previous day, said that they were not aware of any material information that would explain the stock's movement.

One month later, after having received the FDA meeting minutes, the company issued a press release and filed a Form 8-K before the market opened on July 17. The disclosure stated that the meeting had enabled the company to provide FDA with new information to address the long-term safety concern and positively affect the approval status. The disclosure went on to state that there was no formal timeline for approval and that the company continued to reserve its options, but the disclosure provided no additional color about the meeting. Following that disclosure, the company's stock price declined sharply (approximately 16%) in pre-market and early trading. At a pre-scheduled 7:30 a.m. conference call with sell-side analysts, the company discussed the information it provided at the FDA meeting, emailing to analysts, during the course of the call, three supporting studies that had been provided to FDA. Two of the analysts published notes in the hours following the call, indicating there were no safety signals in the program and indicating that the company had submitted an NIH-sponsored study with long-term safety data to support its application. The four other analysts published similar notes. The company's stock price rebounded and finished down by only 6.6% at market close on July 17.

The Charges

The Commission found that the company violated Regulation FD by providing material information about the FDA meetings to sell-side analysts without simultaneously disseminating the information to the public. The Commission identified two separate violations. The first involved general disclosure about the tone of the FDA meeting and the accommodating posture of FDA officials. The second involved disclosure of specific studies submitted to FDA to buttress the company's safety arguments. The order notes that the company did not have policies or procedures relating to Regulation FD compliance.

Observations

Statements about the tone of a meeting and the accommodating posture of FDA officials, in some contexts, might be viewed as too general and vague to be considered material. A 21% increase in the company's stock price, however, likely posed a substantial barrier to the company convincing the SEC that the information was not independently material in this situation. Similarly, the company stated publicly that it had submitted additional information to FDA. A reasonable investor would likely have concluded that information supported the company's application for approval, and, hence, an issuer might assume that the details in the specific studies that it submitted did not alter the total mix of information. Here again, however, substantial swings in the stock price make such an argument challenging. While disclosure judgments must be made in advance of stock price reaction, the market response to disclosure informs subsequent materiality assessments. The SEC's order is a reminder that Regulation FD enforcement actions can be difficult to defend in the face of significant stock price volatility. The order also illustrates the disclosure challenges associated with the back-and-forth of the FDA approval process and the perils of "analyst only" communications.