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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Amicus Faces Shareholder Suit Over Rosy NDA Statements

By **Christine Powell**

Law360, New York (October 8, 2015, 7:25 PM ET) -- Amicus Therapeutics Inc. misled investors about the prospects of a new drug to treat a rare genetic disease, then reversed course two weeks later and sent stock prices plummeting, a shareholder alleged Wednesday in a proposed class action in New Jersey federal court.

Shareholder Lifestyle Investments LLC says that immediately after a meeting with the U.S. Food and Drug Administration on Sept. 15 to discuss a new drug called migalastat, Amicus Therapeutics and CEO John F. Crowley sent out an "upbeat" statement that falsely asserted the company was on track to submit a new drug application by the end of the year. But soon afterward the company backtracked, and its stock price dropped more than 50 percent, the complaint says.

"Just two weeks later, on October 2, 2015, the company abruptly issued a press release contradicting Amicus' stated account of the September 15, 2015 meeting," the complaint says. "While the headline innocuously indicated that Amicus was providing a 'U.S. Regulatory Update,' the press release actually informed the stock market that Amicus' September 15, 2015 press release incorrectly represented the company's meeting with the FDA."

The complaint also accuses Amicus executives of selling shares when the company's stock was inflated, when they knew or should have known that the news release falsely described the company's meeting with the FDA.

Lifestyle Investments says that on the same day as Amicus' Sept. 15 meeting with the FDA to discuss its development of migalastat, an oral drug that would treat Fabry disease, the company issued a statement touting the success of the meeting and announcing the company's intentions to submit an NDA for the drug by the end of 2015.

But when Amicus was given final minutes from the meeting, it "was forced to acknowledge that its September 15 press release was false," the complaint says.

On Oct. 2, Amicus issued a second statement stating that the FDA had actually expressed concerns at the meeting and that the company was no longer on track to submit an application for migalastat by the end of the year.

Amicus stock closed at \$13.75 per share on Oct. 1, but after the announcement on Oct. 2 it closed at \$6.39 per share, the complaint says.

Amicus wasn't following FDA guidance when it sent out the first statement, the complaint said. The FDA advises companies considering submitting an NDA to summarize and share their understanding of meetings with the agency "to ensure that there is a mutual

understanding of meeting outcomes and actions.”

If Amicus had followed the agency's guidance, the complaint says, it would have known that the pre-NDA meeting didn't indicate the company was likely to submit the application by the end of the year.

Lifestyle Investments seeks to represent anyone who purchased Amicus common stock between Sept. 15 and Oct. 1. The complaint asserts claims for violations of the Exchange Act and Rule 10b-5.

A spokeswoman for Amicus said the company intended to fight the lawsuit. “We believe this suit is without merit, and we intend to defend ourselves against it,” she said.

Representatives for Lifestyle Investments didn't immediately respond to requests for comment on Thursday.

Lifestyle Investments LLC is represented by Mark C. Gardy and Jennifer Sarnelli of Gardy & Notis LLP and Jeffrey C. Block and Jacob A. Walker of Block & Leviton LLP.

Counsel information for the defendants was not available.

The case is Lifestyle Investments LLC v. Amicus Therapeutics Inc. et al., case number 3:15-cv-07350, in the U.S. District Court for the District of New Jersey.

--Editing by Brian Baresch.

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