

Dec. 4, 2012

Hagens Berman Investigates Impact of FDA Abiomed Impella Statements, Reminds Investors of Jan. 15, 2013, Lead Plaintiff Deadline in Securities Class Action

Hagens Berman today announced that newly published materials for the upcoming Food and Drug Administration's (FDA) Circulatory System Devices Panel meeting raise new issues regarding Abiomed, Inc. (NASDAQ: ABMD) ("Abiomed") discussions with the FDA concerning the safety and effectiveness of the Impella 2.5 for high-risk PCI and Abiomed's marketing practices. The firm also advises investors who purchased Abiomed stock between Aug. 5, 2011 and Oct. 31, 2012 (the "Class Period") of the Jan. 15, 2013 deadline for moving to be lead plaintiff in a proposed class-action lawsuit against Abiomed regarding alleged securities law violations.

Investors with significant losses who purchased or otherwise acquired Abiomed stock during the class period are encouraged to contact Hagens Berman to discuss moving for lead plaintiff in the pending class-action lawsuit. Investors can contact Hagens Berman Partner Reed R. Kathrein, who is leading the firm's investigation, by calling (510) 725-3000 or by emailing ABMD@Hbsslaw.com.

Any member of the proposed class may move the court to serve as lead plaintiff through counsel of their choice, or may choose to do nothing and remain an absent class member. Class members need not seek to become a lead plaintiff in order to share in any possible recovery.

On Dec. 3, 2012, the FDA released briefing documents for its 515 Program Initiative Advisory Panel meeting, scheduled for Dec. 5-6, 2012, suggesting that the agency will not down-classify the device category for the Impella 2.5 from its current Class III category when used for temporary (six hours or less) prophylactic or non-prophylactic ventricular support during high-risk interventional or surgical procedures not requiring cardiopulmonary bypass. Accordingly, Abiomed may be required to file a premarket approval application requiring it to expend funds for additional clinical trials with the prospect that approval will not be granted.

The NRP 515i Executive Summary, which can be found [here](#), states in part:

"In conclusion, FDA believes there is a lack of valid scientific evidence to support the safety and effectiveness of non-roller type blood pumps for routine temporary (≤ 6 hour) prophylactic or non-prophylactic ventricular support indications during high risk interventional or surgical procedures. Due to this lack of safety and effectiveness data, in addition to the new technology introduced as compared to typical centrifugal pumps, special controls cannot be established to mitigate the risks associated with the use of non-roller type blood pumps for these temporary cardiac support indications."

Hagens Berman has been investigating Abiomed's knowledge of issues raised by the FDA concerning the Impella's marketing since the revelation this November of a Department of Justice (DOJ) investigation and HIPAA subpoena. A class-action securities lawsuit alleging that Abiomed made false or misleading

statements to investors regarding the FDA's concerns about the marketing of the Impella System is pending in the United States District Court for the District of Massachusetts.

"Our investigation centers on what Abiomed executives knew regarding possible off-label marketing of Impella, and to what extent they knew those issues could have a material impact on the company's financial outlook," said Mr. Kathrein. "If investors were left in the dark about serious concerns at the FDA regarding the marketing of Impella, we believe the company is liable under the securities laws for investor losses."

More information about this investigation is available at <http://hb-securities.com/investigations/Abiomed>.

About Hagens Berman

Hagens Berman Sobol Shapiro LLP is an investor-rights class-action law firm with offices in 10 cities. The firm represents whistleblowers, workers and consumers in complex litigation. More about the law firm and its successes can be found at www.hbsslaw.com. The firm's securities law blog is at www.meaningfuldisclosure.com.

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