ABIOMED INC
Form 8-K
May 22, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report: May 22, 2012

(Date of earliest event reported)

ABIOMED, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**04-2743260**
(State or other Jurisdiction of Incorporation)	**(IRS Employer Identification Number)**

0-20584

(Commission File Number)

22 Cherry Hill Drive

Danvers, MA 01923

(Address of Principal Executive Offices, including Zip Code)

(978) 646-1400

(Registrant s Telephone Number, including Area Code)

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)

Item 8.01 Other Events.

Abiomed is filing this 8-K to clarify two meetings held between FDA and Abiomed on February 24, 2012.

A morning meeting was held with the FDA reviewers to present the final results of the PROTECT II study as part of the process to close out the IDE (Investigational Device Exemption). Included in Abiomed s presentation at this meeting were the 30- and 90-day results. The results presented were consistent with those previously disclosed by the Company and originally submitted to the FDA in December 2010. Sub-group analysis was also discussed, including the atherectomy subgroup that was a confounding factor for the PROTECT II trial, as previously disclosed by Abiomed. As reported by Abiomed, vigorous use of atherectomy in the Impella arm led to cardiac enzyme release that qualified in PROTECT II as an MI (myocardial infarction) given the PROTECT II definition of MI as CK-MB > 3x ULN (Upper Limit of Normal).

Abiomed had also requested that some of the meeting time be utilized for an update to the Impella cVAD 510(k) submission. In this context, safety aspects of the technology have to be reviewed with the FDA as a standard part of the 510(k) process.

In a separate afternoon meeting, which was disclosed on the FDA website and held at the request of Abiomed s CEO with Dr. Shuren and his team, the following specific topics were discussed: Registry - Post-Market Surveillance, Clinical Indications/Labeling, Pediatric/HDE Suggestions for Improvement, the 510(k) Process, and Smaller Company Concerns & Recommendations for Improvement. Abiomed s CEO is Chair of AdvaMed s Emerging Growth Companies Committee.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Abiomed, Inc.

By: /s/ Michael R. Minogue
Michael R. Minogue

President and Chief Executive Officer

Date: May 22, 2012