ABIOMED INC
Form 8-K
January 07, 2008

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: January 7, 2008
(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.

On January 7, 2008 the Company announced it had submitted what the Company believes to be the final response to the U.S. Food and Drug Administration (FDA) in connection with its submission for 510(k) clearance for its Impella 2.5 circulatory support device. This response included data related to use of the Impella 2.5 treating 35 patients and the Company believes that the respective data demonstrates the device's safety based on an audit from an independent third party group. The Company stated that the submission also referenced data related to the treatment of hundreds of patients from European peer-reviewed studies. The Company also indicated that the predicate devices were approved without any respective clinical data. The Impella 2.5 device is approved in Europe under CE-mark. The Company expects to receive a response from the FDA on its 510(k) clearance submission sometime before March 31, 2008.

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/ Daniel J. Sutherby

Daniel J. Sutherby
Chief Financial Officer

Date: January 7, 2008