

Edgar Filing: ABIOMED INC - Form 8-K

ABIOMED INC
Form 8-K
August 30, 2007

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: August 27, 2007

(Date of earliest event reported)

ABIOMED, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other Jurisdiction
of Incorporation)

04-2743260
(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))
-

Edgar Filing: ABIOMED INC - Form 8-K

=====
Item 8.01 Other Events.

On August 27, 2007, we received a letter from the U.S. Food and Drug Administration, or FDA, granting us conditional approval to begin a pivotal clinical trial in the United States for our Impella(R) 2.5 Circulatory Support System. This approval is the result of the submission of the clinical results of the safety pilot clinical trial. The pivotal study is conditional upon the Company's submission of additional information to the FDA over the next 45 days and will determine the safety and effectiveness of the Impella 2.5 as compared to optimal medical management with an Intra-Aortic Balloon Pump during "high-risk" angioplasty or when treating patients with low cardiac output and triple vessel disease. The study is approved under category B2 status and the trial sites are eligible for full reimbursement from the Centers for Medicare and Medicaid. A copy of the press release we issued on August 30, 2007 announcing this approval is filed as exhibit 99.1 to this current report on form 8-K and is incorporated herein by reference. The information contained in this report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Act of 1934, whether made before or after the date hereof and regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release dated August 30, 2007.

=====
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: August 30, 2007

Edgar Filing: ABIOMED INC - Form 8-K

=====
Exhibit Index

Exhibit Number -----	Description -----
99.1	Press release dated August 30, 2007.