ABIOMED INC
Form 8-K
June 30, 2005

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: June 23, 2005

(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) 777-5410

(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:

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

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

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

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

Item 8.01 Other Events.

The Circulatory System Devices Panel of the U.S. Food and Drug Administration (FDA) met on June 23, 2005 to review ABIOMED s submission requesting approval of its AbioCor fully implantable artificial heart under a Humanitarian Device Exemption (HDE). Such an approval authorizes a company to market and sell a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. The application, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. The AbioCor is designed to replace the pumping function of the heart of patients for whom there is no other viable option available. The Panel reviewed the clinical outcomes of fourteen patients enrolled during the AbioCor clinical trial and voted that the AbioCor did not meet the requirements for an HDE device and requested additional information. The FDA will review the recommendations from the panel before it reaches a final decision.

Item 9.01 Financial Statements and Exhibits

(c) *Exhibits.*

Exhibit Number	Description
99.1	Press release dated June 23, 2005

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/ Charles B. Haaser
Charles B. Haaser
Controller
Principal Accounting Officer
Principal Financial Officer

Date: June 29, 2005

Exhibit Index

Exhibit Number	Description
99.1	Press release dated June 23, 2005