

ABIOMED INC  
Form 8-K  
September 08, 2004

**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: September 1, 2004**

(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) 777-5410**

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(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))
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**Item 8.01                    Other Events**

On September 1, 2004, ABIOMED, Inc. submitted, pending acceptance for filing, to the United States Food and Drug Administration for market approval of the AbioCor Implantable Replacement Heart under a Humanitarian Device Exemption (HDE). Approval under an HDE would make the AbioCor commercially available to treat annually a defined subset of not more than 4,000 irreversible end-stage heart failure patients.

The full text of the Company's press release reporting this filing is attached as Exhibit 99.1 to this report and incorporated herein by reference.

**Item 9.01                    Financial Statements and Exhibits**

(c) Exhibits

99.1                    Press release dated September 8, 2004

**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: September 8, 2004

**Exhibit Index**

| <b>Exhibit Number</b> | <b>Description</b>                    |
|-----------------------|---------------------------------------|
| 99.1                  | Press release dated September 8, 2004 |