ABIOMED INC
Form 8-K
December 07, 2012

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 (Date of earliest event reported): December 6, 2012

ABIOMED, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-09585**	**04-2743260**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

22 Cherry Hill Drive

Danvers, MA 01923

(Address of principal executive offices) (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 (see General Instruction A.2. below).

¨ 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 December 6, 2012, we issued a press release announcing that the U.S. Food and Drug Administration s (FDA) Circulatory System Devices Panel voted to retain Class III status for the temporary ventricular support devices within the non-roller type cardiopulmonary bypass blood pumps category, under which our Impella products are categorized. A copy of the press release is attached as exhibit 99.1 to this current report on Form 8-K and incorporated herein by reference.

Dr. David Weber our Chief Operating Officer, Dr. Jeffrey Popma of Beth Israel Deaconess Medical Center in Boston and Dr. William O Neill of Henry Ford Hospital led a presentation to the FDA s Circulatory System Devices Panel related to the classification of our Impella devices on December 6, 2012. A copy of the slides used in the presentation is attached as exhibit 99.2 to this current report on Form 8-K and incorporated herein by reference. Also attached as exhibit 99.3 to this current report on Form 8-K and incorporated herein by reference is a copy of a summary we provided to the FDA on December 6, 2012 listing clinical and scientific publications on the Impella 2.5, Impella 5.0 and Impella LD.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Number	Description
99.1	Press release dated December 6, 2012.
99.2	Abiomed Presentation to FDA 515i Panel Classification Determination for Non-roller Type CPB Pumps dated December 6, 2012.
99.3	Impella Clinical Literature Summary.

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/ Robert L. Bowen
Robert L. Bowen
Vice President and Chief Financial Officer

Date: December 7, 2012