ABIOMED INC
Form 8-K
September 21, 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): September 21, 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 7.01 Regulation FD Disclosure.

Abiomed is filing this current report on Form 8-K in response to recent investor questions received at a series of investor conferences and meetings over the past several weeks.

1) **Medicare National Coverage Determination**: We believe, after recent communication and review of all coverage policy reference information from the Centers for Medicare & Medicaid Service (CMS), which administers the Medicare insurance program, that there is currently no consideration for a National Coverage Decision for the Impella technology.

2) **Current Procedural Terminology (CPT) Codes**: CPT codes are used for physician reimbursement. The American Medical Association (AMA) recently released new codes for Impella technology for insertion, repositioning, and removal. Payment rates will be released in November 2012 and physicians will begin using the new coding on January 1, 2013. Investors should reference Abiomed s press release dated September 4, 2012.

3) **DRG reimbursement**: Impella has been reimbursed under the Medicare DRG system since the device s 510(k) marketing clearance in 2008. Each year, the DRG codes for Impella (DRGs 216, 217, and 218) have been assessed and reaffirmed by CMS. For CMS FY2013 (beginning October 2012), the DRG codes and rates have been determined; in addition, CMS has indicated that Impella-related DRG groupings for FY2014 will remain status quo during the Medicare system-wide transition from ICD9 to ICD10 codes.

4) **LVAD MEDCAC Meeting**: A CMS Medicare Evidence Development Coverage and Advisory Committee (MEDCAC) meeting will be held November 14, 2012 to discuss the Management of Heart Failure with Use of Ventricular Assist Devices (VADs). Percutaneous ventricular assist devices are not on the meeting agenda and CMS has confirmed orally to Abiomed that the focus of the meeting is exclusively on implantable ventricular assist devices.

5) **515 Program Initiative**: As stated in the Center for Devices and Radiological Health (CDRH) 2012 Strategic Priorities as goal 1.1.1.2, CDRH will continue to take steps to address Class III device types currently allowed to enter the market through the 510(k) process - by December 31, 2012, clear within CDRH proposed rules for all remaining Class III pre-amendment medical devices. There are 26 remaining categories, one of which is 21 CFR 870.4360, nonroller-type cardiopulmonary bypass blood pump which includes Impella products. New legislation requires the FDA to conduct an Advisory Panel for each category prior to issuing a proposed classification determination. Products in categories under review will remain on the market until clinical data has been reviewed and/or generated after an extended period of time. Abiomed has an existing body of clinical evidence for Impella and is confident in its ability to work with the FDA on any additional data requests. Other categories to be reviewed are intra-aortic balloon pumps (21 CFR 870.3535) and Extracorporeal Membrane Oxygenation (21 CFR 868.5610).

6) **PROTECT II**: In the final PROTECT II FDA Protocol, section 7.10 SUBGROUP ANALYSES, it states: Detailed classification and description of the subgroup variables will be defined in the statistical analysis plan (SAP) prior to database locking. The Statistical Analysis Plan (SAP) is a separate document from the FDA Protocol, in which atherectomy was pre-specified.

7) **Impella CP**: The Impella CP and Impella 2.5 are both 510(k) cleared for identical indications. Investors should reference Abiomed s press release dated September 10, 2012.

The information contained in this Item 7.01 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.

Forward looking statements

The information contained in this Item 7.01 contains forward-looking statements, including statements regarding anticipated regulatory actions and their impact on our products, commercial growth, and future opportunities. Our actual results may differ materially from those anticipated in

these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, anticipated future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, future capital needs and uncertainty of additional financing, and other risks and challenges detailed in our filings with the Securities and Exchange Commission, including our annual report filed on Form 10-K and our most recently filed quarterly report on Form 10-Q. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this current report. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this current report or to reflect the occurrence of unanticipated events.

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
Chief Financial Officer

Date: September 21, 2012