ABIOMED INC
Form 8-K
March 21, 2016

**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 (Date of earliest event reported): March 21, 2016**

**(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)** |

**001-09585**

**(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)

**Item 7.01 Regulation FD Disclosure.**

Today, ABIOMED, Inc. ( the Company ) announces that the Company and the Food and Drug Administration ( FDA ) have agreed on the indication for use for emergency patients suffering from cardiogenic shock following acute myocardial infarction or cardiac surgery for the Pre-Market Approval ( PMA ) for the Impella 2.5 , Impella® CP Impella 5.0 and Impella LD devices. Based on the information available to the Company to date, including multiple discussions with the FDA, the Company no longer anticipates the requirement for an FDA advisory panel prior to the PMA approval for the safety and effectiveness of the Impella 2.5 , Impella CP®, Impella 5.0 and Impella LD devices for this indication.

The data submitted to the FDA in support of the PMA included an analysis of 415 patients from the RECOVER 1 study and the U.S. Impella registry (cVAD Registry™), as well as an Impella literature review including 692 patients from 17 clinical studies. A safety analysis reviewed over 24,000 Impella patients using the FDA medical device reporting ( MDR ) database, which draws from seven years of U.S. Impella experience. The Company believes this is the most comprehensive review ever submitted to the FDA for circulatory support in the cardiogenic shock population.

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, as amended (the Exchange Act ), 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, as amended, or the Exchange Act, 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 Current Report on Form 8-K contains forward-looking statements, including the statement that the Company no longer anticipates the requirement for an FDA advisory panel for the PMA approval for the safety and effectiveness of the Impella 2.5 , Impella CP®, Impella 5.0 and Impella LD devices for the indication discussed in this Item 7.01. Each forward-looking statement contained in this Current Report on Form 8-K is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, uncertainties associated with the process of obtaining PMA approval and the risks identified under the heading Risk Factors in the Company s Annual Report on Form 10-K for the year ended March 31, 2015 and the Company s most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2015, each filed with the Securities and Exchange Commission, as well as other information the Company files with the SEC. We caution investors not to place considerable reliance on the forward-looking statements contained in this Current Report on Form 8-K. You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this Current Report on Form 8-K speak only as of the date of this filing and the Company undertakes no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

**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/ Michael J. Tomsicek
Michael J. Tomsicek
Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)
Date: March 21, 2016