ABIOMED INC
Form 8-K
February 04, 2019

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): February 4, 2019

(Date of earliest event reported)

ABIOMED, Inc.

(Exact name of registrant as specified in its 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, 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)
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

Statement from Abiomed on RP Notification

Abiomed is committed to proactively sharing data to inform the medical community of best practices for use of the Impella RP® heart pump and to continue to improve outcomes for patients.

The Impella RP is the only device with FDA PMA approval for right side support. FDA studies demonstrate that proper use and timely implantation of Impella RP increases survival with the potential for recovery of the right ventricle [i] [ii]. The data below was published in December, 2018:

Impella RP PMA Cohort Study Results (N=60)

		Survival Rates
PMA Subjects (RR + CAP + HDE PAS)	full cohort (N=60)	73% (44/60)
Cohort A (N=31)		77% (24/31)
Cohort B (N=29)		69% (20/29)

Journal of Heart and Lung Transplant, December 2018(37)

On January 31, 2019, Abiomed proactively sent physicians who use Impella RP post-approval study (PAS) data that provides additional evidence of the benefits of following proper protocols for placement of Impella RP. The data is summarized in the table below and demonstrates the importance of early placement of Impella RP, and the importance of following proper inclusion and exclusion criteria when selecting patients for Impella RP.

The PMA cohort (n=60) had 73% survival and the PAS cohort (n=23) is currently at 17%. This PAS population has 70% (16/23) outside the recommended treatment protocol inclusion and exclusion criteria, and as a result survival rates are lower. These patients were critically ill and, in some cases, had been in profound shock for more than 48 hours. As such, these patients were statistically sicker and may not have been appropriate candidates to benefit from right side mechanical circulatory support.

Characteristics	**Impella RP Pre-Market Application (PMA) Study (N=60 Patients)**	**Impella RP Post-Market Approval (PMS) Report (N=23 Patients)**	**P-Value**
Age			
Mean±SD(N)	58.58±15.12(60)	65.61±13.72(23)	0.056
Did the patient experience an in-hospital cardiac arrest prior to Impella implant	0.00% (0/60)	56.52% (13/23)	<.001
At the time of Impella implant did the patient receive CPR/ACLS	0.05% (3/60)	30.43% (7/23)	<.001
	0.00% (0/60)	14.29% (3/21)	0.016

Was there evidence of hypoxicischemic brain injury prior to Impella implant			
Was the patient supported with inotrope or vasopressors prior to Impella implant	98.33% (59/60)	86.96% (20/23)	0.063
If yes, Indicate total number of inotrope or vasopressors			
Mean±SD(N)	3.37±1.24(59)	4.38±1.56(13)	0.014
Median	3.00	4.00	
Range (Min, Max)	(1.00,6.00)	(2.00,8.00)	
Patients in shock >=48 hours	0.00% (0/34)	26.09% (6/23)	<.001
IABP used prior to Impella implant	0.00% (0/60)	30.43% (7/23)	<.001

Abiomed encourages all clinicians to review proper inclusion and exclusion criteria for Impella RP. To help physicians determine if Impella RP is right for their patients, Abiomed has created an FDA-approved checklist to guide treatment decisions and encourages the use of physician guidelines such as the National Cardiogenic Shock Initiative (https://www.henryford.com/cardiogenicshock/protocol) and the Shock Care Pathway Algorithms (http://www.onlinejacc.org/content/72/16/1972). The checklist is available at https://www.protectedpci.com/resources/. Right side failure remains a more difficult diagnosis than left side failure based on clinical experience and lower occurrence in clinical practice.

As a leader in post-market surveillance to improve patient outcomes, Abiomed tracks outcomes on nearly 100% of its Impella RP patients. The manufacturers of other technologies for right side support are cleared for less than 6 hours of support (ECMO, TandemLife®) and as a result, do not have regulatory responsibility to track and publically report a post approval study (PAS) on their patient outcomes. Abiomed will

continue to focus on improving clinical outcomes for both left and right ventricular failure by advancing innovation, identifying best practices and providing 24x7 on-site and on-call support to address the clinical crisis of cardiogenic shock in today s healthcare system.

[i] *Journal of Heart and Lung Transplant, December 2015(34)*

[ii] *Journal of Heart and Lung Transplant, December 2018(37)*

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/ Todd A. Trapp
Todd A. Trapp

Vice President and Chief Financial Officer

Date: February 4, 2019