



Abiomed Expands Product Portfolio with Acquisition of Cardiopulmonary Support Technology (ECMO) to Improve Outcomes for Patients

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DANVERS, Mass.--(BUSINESS WIRE)--Apr. 29, 2020-- [Abiomed](#) (NASDAQ: ABMD), maker of the [Impella](#) heart pump, has acquired Breethe, developer of a novel extracorporeal membrane oxygenation (ECMO) system that will complement and expand Abiomed's product portfolio to more comprehensively serve the needs of patients whose lungs can no longer provide sufficient oxygenation, including patients suffering from cardiogenic shock or respiratory failure such as due to ARDS, H1N1, SARS, or COVID-19. ECMO has also been utilized as a primary method of oxygenation and hemodynamic support for pediatric patients.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20200429005975/en/>



Patients who require ECMO therapy have a severe and life-threatening illness that stops their lungs from working properly. The system is connected to patients through tubes (cannulae) and is an external respiratory assistance device that takes venous blood, removes carbon dioxide and adds oxygen, much like a human lung. Oxygenated blood is then sent back to the patient. Each year, more than 20,000 patients receive ECMO therapy in the United States.

Abiomed recognizes the need for ECMO therapy for patients in need of oxygenation and has supported approximately 10,000 ECMO plus Impella (ECPella™) patients with cardiogenic shock over the past 10 years. In Japan, more than half of Impella patients receive ECPella for hemodynamic and oxygenation support.

Breethe's product is a first-of-its kind, easy-to-use compact ECMO system with an integrated oxygen concentrator that eliminates the need for bulky oxygen tanks to promote easier patient ambulation. It has a novel design that is intuitive for health care providers to set up, manage, and monitor. Abiomed invested in Breethe in mid-2019. Breethe has applied for 510(k) clearance by the Food and Drug

The Breethe system has an integrated oxygen concentrator removing the need for bulky, heavy tanks and multiple wires enabling easier patient mobility. (Photo: Business Wire)

Administration (FDA).

Breethe's founder and the Hales Distinguished Professor of Surgery at University of Maryland School of Medicine, Bartley Griffith, MD, is a renowned leader in multiple areas of adult cardiac surgery including mechanical circulatory support. Dr. Griffith has collaborated with Abiomed for a number of years and served as the principal investigator of [RECOVER_I](#). With decades of experience, Dr. Griffith and his team designed the cutting-edge Breethe system to improve patient outcomes, improve quality of life and reduce total cost of care by changing the way oxygenation is delivered.

"Abiomed is the best positioned company to build on the legacy of what we started," said Dr. Griffith. "I am confident that the addition of Breethe's technology into Abiomed's product portfolio will further enhance Abiomed's ability to improve outcomes for their patients and serve a new patient population."

"This acquisition is a natural progression toward improving patient care," said Matthew D. Bacchetta, MD, associate professor, Department of Thoracic Surgery at Vanderbilt University. "Breethe's compact and all-in-one technology aims for improved patient ambulation, which can improve outcomes and promote active rehabilitation for patients with cardiopulmonary diseases."

"Breethe will integrate with Abiomed and our manufacturing, quality, sales, engineering and research capabilities, including Abiomed's best-in-class Clinical Support Center," said Michael R. Minogue, Abiomed's Chairman, President and Chief Executive Officer. "This acquisition aligns with our principles of leading in technology and innovation, putting patients first and striving to continually improve outcomes. Physicians have asked Abiomed to bring this technology into our portfolio because of our ability to support patients, teach best practices, and collect critical data for research. This ECMO technology will allow us to treat cardiogenic shock patients who are already being supported with Impella, add pediatric offerings and treat a new patient population with respiratory failure."

This acquisition provides Abiomed with the opportunity to innovate traditional ECMO technology, focusing on patient ambulation and recovery from acute respiratory failure. For many patients in cardiogenic shock, Impella is the optimal technology because it unloads the left ventricle, perfuses end

organs and allows the heart to rest and recover. Abiomed recognizes patients in cardiogenic shock may also need oxygenation. ECMO perfuses the end organs but does not unload the left ventricle, which increases the oxygen demand of the myocardium (heart muscle) in these patients. For patients in cardiogenic shock, Impella with ECMO (ECPella) work together to unload the heart and oxygenate the body.

Multiple studies support the association of ECPella therapy to improve outcomes for patients who are suffering from cardiogenic shock and require oxygenation. The [European Journal of Heart Failure](#), [ASAIO](#), and the [Journal of the American College of Cardiology](#) have published studies that examine a combined 4,126 patients and conclude use of ECPella was associated with increased survival rates, as compared to patients who were treated with ECMO only. (See figure 1.) In addition to higher survival, the study in the *European Journal of Heart Failure* by Pappalardo et al. found higher rates of heart recovery with ECPella use than with ECMO only (62% vs 36%; p=0.048).

Terms of the acquisition are not being disclosed at this time.

ABOUT IMPELLA HEART PUMPS

The Impella 2.5[®] and Impella CP[®] devices are U.S. FDA PMA approved to treat certain advanced heart failure patients undergoing elective and urgent percutaneous coronary interventions (PCI) such as stenting or balloon angioplasty, to re-open blocked coronary arteries. The Impella 2.5, Impella CP, Impella CP with SmartAssist[®], Impella 5.0[®], Impella LD[®], and Impella 5.5[™] with Smart Assist[®] are U.S. FDA approved heart pumps used to treat heart attack or cardiomyopathy patients in cardiogenic shock, and have the unique ability to enable native heart recovery, allowing patients to return home with their own heart. The Impella RP[®] is U.S. FDA approved to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. Impella is the most studied mechanical circulatory support device in the history of the FDA with more than 10 years of FDA studies, real world clinical data on more than 140,000 patients and more than 650 peer-reviewed publications.

In Europe, the Impella 2.5, Impella CP and Impella CP with SmartAssist are CE marked for treatment of high-risk PCI and AMI cardiogenic shock patients for up to 5 days. Impella 5.0 and Impella LD are CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 10 days. The Impella 5.5[™] with Smart Assist[®] is CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 30 days. The Impella RP is CE marked to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, open-heart surgery, or refractory ventricular arrhythmia.

To learn more about the Impella platform of heart pumps, including their approved indications and important safety and risk information associated with the use of the devices, please visit www.impella.com.

ABOUT ABIOMED

Based in Danvers, Massachusetts, USA, Abiomed, Inc. is a leading provider of medical devices that provide circulatory support. Our products are designed to enable the heart to rest by improving blood flow and/or performing the pumping of the heart. For additional information, please visit www.abiomed.com.

Abiomed, Impella, Impella 2.5, Impella 5.0, Impella LD, Impella CP, Impella RP, and Impella Connect are registered trademarks of Abiomed, Inc., and are registered in the U.S. and certain foreign countries. Impella BTR, Impella 5.5, Impella ECP, CVAD Study, DTU STEMI Study and SmartAssist are pending trademarks of Abiomed, Inc.

ABOUT BREETHE

Breeth has filed for, but not received, 510 (k) clearance for its OXY-1 System. The materials contained herein about Breeth's future products are intended for investor information purposes only and should not be used for the purposes of providing medical treatment. Nothing herein should be construed as a claim of safety or efficacy with respect to future products or indications.

FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including statements regarding development of Abiomed's existing and new products, the company's progress toward commercial growth, and future opportunities and expected regulatory approvals. The company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with the scope, scale and duration of the impact of the COVID-19 pandemic, development, testing and related regulatory approvals, including the potential for future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, litigation matters, future capital needs and uncertainty of additional financing, and other risks and challenges detailed in the company's filings with the Securities and Exchange Commission, including the most recently filed Annual Report on Form 10-K and the filings subsequently filed with or furnished to the SEC. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. The company undertakes 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 release or to reflect the occurrence of unanticipated events.

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