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The Most Powerful Name in Corporate News

Transcatheter Device for Diastolic Heart Failure

George Fazio - *CEO*

About DC Devices, Inc.
DC Devices, Inc. is dedicated to revolutionizing the treatment of heart failure with first-in-class structural heart devices. The company has developed the world's first transcatheter device designed to treat diastolic heart failure (DHF), also known as heart failure with preserved ejection fraction (HFpEF). The InterAtrial Shunt Device (IASD™) System is designed to relieve elevated left atrial pressure (LAp), the main cause of DHF symptoms. The IASD System is designed to be cost-effective and is intended to dramatically improve patients' quality of life, while significantly reducing hospitalization costs. DC Devices is funded by Accelmed, Third Rock Ventures, General Catalyst Partners, Lumira Capital, and an undisclosed strategic investor. For more information, please visit www.dcdevicesinc.com

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: ***Mr. Fazio, your site indicates that "DC Devices is Revolutionizing the Treatment of Heart Failure with First in Class Structural Heart Devices." How so?***
Mr. Fazio: The reason we call our device First-in-Class is that it is the first device-based treatment option for half of all heart failure patients. That half of heart failure is called diastolic heart failure, otherwise known as heart failure with preserved ejection fraction. Today, there are effective device and drug treatments for the other half of heart failure, called systolic heart failure, but no device technology is available for diastolic heart failure patients. From that perspective, it is a First-in-Class device treating a very large unmet need in the medical space.

CEOCFO: ***As a layperson would I know the difference in the types of heart failure or is that more technical or medical than the average person understands?***
Mr. Fazio: It is probably more technical than the average unaffected person would appreciate mainly because the major symptoms and the survival rates between systolic and diastolic heart failure are very similar; it is mainly the cause of the heart failure that is different.

CEOCFO: ***When someone goes to the hospital or when a doctor looks are they able to easily recognize the difference?***
Mr. Fazio: Yes, after a brief set of tests, a hospital, emergency room, or a clinician would be able to readily differentiate between the two.

CEOCFO: ***Would you tell us about the device?***
The device was invented in Australia by Dr. David Celermajer. His idea was to treat patients with diastolic heart failure by lowering their left atrial pressure. It is that elevated pressure in the heart that causes the onset of major symptoms and puts patients in the hospital. An interventional cardiologist implants our device in a very minimally invasive manner, there is no need for surgery, and the procedure itself is short in duration. We believe our device will alleviate significant symptoms caused by heart failure and improve patients' quality of life while reducing hospital costs.

CEOCFO*: What metal is the used for your device?*
Mr. Fazio: It is a metal called nitinol, which is commonly used in medical devices like stents, which most people are familiar with for treating blockages in the arteries of the heart.

CEOCFO: *Where are you in development and commercialization?*
Mr. Fazio: We are in our fifth year as a company and we have completed all of our early preclinical and clinical work. This has put us in the position to begin a clinical study, which will be used to commercialize the device in Europe. We are currently enrolling patients in Europe and Australia.

CEOCFO: *Is Europe easier?*
Mr. Fazio: We approached Europe first because it is a more predictable path and we are able to commercialize the device sooner.

CEOCFO: *Have there been attempts to create a solution for this problem in the past or currently that you are aware of that might be competition for you?*
Mr. Fazio: There were no other attempts to do specifically what we are doing in a minimally invasive manner; there have been surgical approaches and concepts in the past which would have achieved the same end point, to lower left atrial pressure in the heart, but we were the first to do it through a catheter without the need for surgery.

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- George Fazio

CEOCFO: *What has been the interest in the medical and investment community?*
Mr. Fazio: Specific to our area there has been tremendous interest. We happen to be in the sweet spot of two areas of great interest for investors and for strategic players in the marketplace. Those areas are heart failure and what is referred to as structural heart. Structural heart encompasses pretty much all therapeutic transcatheter devices used in the heart. The combination of a structural heart or transcatheter approach to heart failure is an area of significant interest.

CEOCFO: *Are you funded for the next steps?*
Mr. Fazio: Yes, we are funded for the next three years and that would bring us to our approval outside the United States and commercialization in targeted markets while beginning work with the FDA toward a US approval as well.

CEOCFO: *What gave you the confidence that this device was going to work?*
Mr. Fazio: What was appealing to me is that it was well known that tracking increases in left atrial pressure and monitoring left atrial pressure were very important in the development and worsening of heart failure. A device that could acutely lower left atrial pressure, in a permanent way, and break that cycle of worsening is very appealing and helpful to patients suffering with this terrible syndrome. Secondly, the procedure itself is an elegant approach to diastolic heart failure because it's a procedure that physicians are comfortable doing. It seemed intuitive that this procedure could be done relatively quickly and provide a possible therapy to a large class of patients that need a new option. Our device is a simple and elegant way to help that large group of patients with no other alternatives today.

CEOCFO: *What have you learned from previous experience that is most helpful as you have developed the company so far?*
Mr. Fazio: Personally, it is important to surround yourself with a team that has a great depth of experience in the different facets of bringing a medical device technology to market. It is a challenging process but when you are working with a group of people that are exceptional at what they do, you avoid repeating mistakes that others have already made in the past. Building and supporting a first class team is the most important part of what I do.

CEOCFO: *What is the timetable?*
Mr. Fazio: The timetable for the company is to continue our evolution toward becoming a commercial entity. The key milestones are approval of the device in Europe while at the same time beginning work towards that same endpoint with the FDA in the US. With those regulatory approvals we will become a significant structural heart device company in the med-tech sector.

CEOCFO: *Why does DC Devices standout?*
Mr. Fazio: We have a First-in-Class device for a large population of untreated patients. We are building a significant intellectual property portfolio as well. I believe that the combination of those pieces is a very exceptional opportunity in the medical device space.

CEOCFO: *Final thoughts?*
Mr. Fazio: We are grateful to have significant contributions from a tremendous Board of Directors and investors who believe in our mission to improve the lives of patients suffering with Heart Failure around the world.

BIO: Mr. George J. Fazio has been Chief Executive Officer and President at DC Devices Inc. since 2010. Prior to DC Devices, Mr. Fazio held numerous leadership positions at St. Jude Medical from October 1992 through December 2009. His roles at St. Jude Medical included: President of the U.S. Division, President of the Cardiovascular Division, President of the Cardiac Surgery Division, and President of Europe, Middle East, Africa (EMEA) residing in Belgium. Mr. Fazio also served as President of Health Care Services where he built the National Accounts function for managing cross-divisional contracting and General Manager of Canadian Operations where he brought St. Jude Medical's operations direct from a distributor-based distribution model while residing in Toronto, Canada. Prior to St. Jude Medical, Mr. Fazio held several positions of increasing responsibility at the Davis & Geck Division of American Home Products from 1984 to 1992 including Marketing-Product Manager, Regional Sales Manager, Sales Training Manager and Sales Representative. Mr. Fazio is currently serving on the Board of Directors for BioVentrix Inc. Mr. Fazio holds a B.S. from the State University of New York at Albany and an MBA from the Fordham University Graduate School of Business.

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