Medtech Insight
Pharma intelligence | informa

Start-Up Spotlight: CorInnova, Taking Robotics To Heart To Reduce LVAD-Linked Stroke

24 Jan 2018 | **ANALYSIS**

by Bob Kronemyer | bkronemyer@frontier.com

Executive Summary

EpicHeart by CorInnova is an advanced cardiac compression device that combines the advantages of a flexible endoskeleton and soft robotics to provide biventricular cardiac support for heart failure patients. Because the device does not touch the blood, many adverse events such as stroke and gastrointestinal bleeding associated with existing cardiac-assist technologies are eliminated. Delivered minimally invasively, the potential patient population is also much larger than for a chronic left ventricular assist device.

There has been no improvement in the stroke rate associated with the use of left ventricular assist devices (LVADs) over the past 15 years because blood vigorously attacks the surfaces of these devices, generating thrombi and strokes, according to William Altman, CEO of **CorInnova Inc.**, a start-up developing a soft robotic heart-assist device that could potentially promote heart recovery.

"Blood is the most aggressive organ in the body. It is very good at attacking foreign objects that touch the blood," he told *Medtech Insight*.

CorInnova's heart-assist product, *EpicHeart*, overcomes blood's natural protective response by having no blood contact, which should result in a significant decrease in adverse events, most notably stroke, compared to current LVADs.

EpicHeart is a soft robotic, thin-film polyurethane device shaped like a cup and has a self-expanding nitinol frame, which is thin enough to fit within the pericardial sac that surrounds the heart, but also collapsible and springy enough to fit within a one-inch tube for minimally invasive implantation.

The temporary implant is placed in patients with severe heart failure, either on an acute or long-term basis. The first indication is intended for a placement of less than 30 days in an acute heart failure setting to stabilize the patient, including simply recovering and being discharged with no further intervention.

"For post-severe heart attack, EpicHeart provides support for the heart that has been damaged and increases its cardiac output, while at the same time stabilizing the dead tissue, so the heart can create a scar over two to three weeks," Altman explained. "Then, when you remove the device, the heart will have natural motion and should not develop heart failure."

Altman pointed out that EpicHeart dramatically expands the treatable patient population, because even if it does not promote heart recovery, it is much less invasive to implant than other heart-assist devices and there are far fewer significant adverse events because of the lack of blood contact.

Patients targeted for EpicHeart are "bridge to recovery" and post-heart attack treatment to prevent heart failure. Between the two categories, there are roughly 200,000 to 300,000 patients yearly in the U.S. and Europe. "This is over 20 times the number of people who are being treated with a LVAD," said Altman, who noted that the annual market potential for EpicHeart exceeds $20bn.

CE mark for EpicHeart is expected around 2022, followed two years later by US premarket approval.

CE mark for the product is expected around 2022, followed two years later by US premarket approval.

The principal founder of CorInnova is John Criscione, a professor of biomechanical engineering at Texas A&M University in College Station. While pursuing his PhD at Johns Hopkins University in the late 1990s, Criscione experimented with beating heart cells, when he discovered that beating heart cells in petri dishes survived many times longer than heart cells whose movement had been stopped. In fact, nearly all heart cells prevented from moving died. "Dr. Criscione became aware that this cell movement is intrinsic and necessary for cardiac cells to survive," Altman recounted.

Further research by Criscione validated the importance of motion in cardiac cells for heart recovery following a severe heart attack.

"Dr. Criscione's objective was to correct the motion of the heart with a mechanical device," Altman said. "However, it took several years for him to figure out how to make a device easily implantable around a heart. He ended up using thin film polyurethane chambers encased around a nitinol basket framework, as opposed to thicker meshes that others used."

The cup-like device could also be implanted with a deployment tool, but Criscione eventually made it easier by bending the wires, so that when the device exits the tube, it naturally surrounds the heart within 45 seconds.

"EpicHeart also promotes recovery and prevents the further progression of heart failure, or even the beginning of heart failure, by moving in such a way that it enhances the natural motion of the heart," Altman conveyed. "This is in contrast to prior cardiac devices that squeeze the heart, but do so in an unnatural way and deform the heart shape."

Altman said EpicHeart is the only device that has been designed to emulate the shape of the heart at both diastole (when the heart is relaxed) and at systole (when the heart is contracted).

The other cofounder of CorInnova is Dennis Robbins, chairman of the board of directors of CerSci Therapeutics Inc. (nonopioid medicines to treat pain), who helped Criscione incorporate the company.

Altman, who was a Rhodes Scholar in politics and economics at Oxford University from 1980 – 1982, previously was a management consultant in healthcare at McKinsey & Company from 1985 – 1989. He also served as CEO of Kardia Therapeutics Inc. (stem cell research for heart failure) from 2001 – 2003.

CorInnova has 21 issued and 14 pending patents, and will pay a standard royalty to Texas A&M University.

EpicHeart consists of three user components: the implantable device that surrounds the heart; an internal/external driveline that provides the air and the signaling capability; and an external battery-operated pneumatic driver.

For the in-patient procedure under general anesthesia and fluoroscopy, the device is first preloaded into approximately a one-inch tube. A cardiothoracic surgeon then makes an incision between two left side ribs, keeping the two ribs apart by about 1.5 inches with a separate instrument. Next, the tube is inserted between the two ribs and threaded up against the apex of the heart.

The surgeon then makes about a 1-inch incision in the pericardium at the apex of the heart. The device is then pushed out from the tube into the pericardial sac. “The frame flowers open in a shape consistent with the heart shape as you push it out of the tube, without any deployment tool at all,” Altman stated.

It takes less than one minute to place EpicHeart around the heart. Afterward, a special set of inner chambers is filled with saline to conform exactly to the heart’s shape and to provide even pressure throughout. Electrodes inside the device touch the heart.

The pericardial sac around the driveline is then secured around the driveline and the chest closed. Afterward, the driver is activated and air inflates the device in synchrony with the heartbeat to provide cardiac assist.

The entire procedure takes about 90 minutes versus eight hours for a LVAD. “Our surgeons tell us that

CorInnova Inc.

JLABS @ TMC

2450 Holcombe Boulevard, Suite J

Houston, Texas 77021

Phone: (346) 772-0345

Website: www.corinnova.com

Contact: William Altman, CEO

Industry Segment: Cardiovascular

Business: Compression device employs integrated air muscles pneumatically actuated by software, in synchrony with the heartbeat, to increase cardiac output.

Founded: July 2004

Founders: John Criscione, MD, PhD (Texas A&M University); Dennis Robbins, PhD (CerSci Therapeutics Inc.)

Employees: 7

Financing to Date: $8.4m

Investors: Private Investors; Wellcome Trust; National Heart, Lung and Blood Institute (NHLBI); National Science Foundation (NSF); Texas Emerging Technology Fund

Board of Directors: William Altman; John Criscione; Dennis Robbins, Michael Tiner (Tanglewood Investments)

Scientific Advisory Board: Daniel Burkhoff, MD, PhD (Columbia University School of Medicine);

EpicHeart is the easiest cardiac-assist device to implant, ever," Altman said. "Many surgeons have also said that EpicHeart may be a device that could be implanted by a general surgeon at a secondary surgery center."

The anticipated hospital length of stay is four to six days, which is comparable to minimally invasive aortic valve replacement, while existing chronic LVADs require a 20 to 30 day length of stay.

Removal of EpicHeart involves basically the same surgery and the same length of time, with perhaps the addition of a surgical tool to separate the device from the pericardial sac.

"Our target is for the implant to remain in the body for one to two weeks," Altman said.

The first sheep animal safety study and related sheep efficacy studies to test the potential for heart recovery are slated for this year.

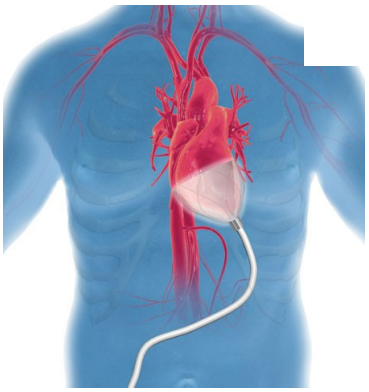
CorInnova's closest competitor is **Abiomed Inc.** which is conducting a study of its *Impella* heart pump for support post-heart attack to reduce infarct (dead tissue) size. "However, the pump touches the blood and can potentially trigger a stroke," Altman noted. "Unlike EpicHeart, the pump does not prevent aberrant motion of the heart and is unable to stabilize the heart wall."

A second rival, **NuPulse Inc.**, has in development a blood contacting mechanical balloon pump device that travels down the descending aorta: *NuPulseCV iVAS* (intravascular ventricular assist system). "This device also makes contact with blood," Altman said. "Plus, the device supports only one ventricle and is not targeting support for patients after severe heart attack, so the device is limited to only a portion of our potential patient population."

When EpicHeart eventually becomes commercially available, a direct sales force will be employed, with pricing similar to an existing LVAD, which is about $100,000, including the pneumatic driver. Reimbursement is also likely under the same code as LVAD.

William Abraham, MD (Ohio State University School of Medicine); William Cohn, MD (Johnson & Johnson Medical Devices), Susan Alpert, MD, PhD (SFA Consulting LLC); Ulrich Jorde, MD (Montefiore Medical Center); Dan Meyer, MD (University of Texas Southwestern Medical Center); William Hunter, MD (Cardiome Pharma Corp.)

CorInnova's EpicHeart heart-assist system



Source: CorInnova, Inc.

THE IMPLANTABLE DEVICE SURROUNDS THE HEART AND A CONNECTING LINE INFLATES THE DEVICE IN SYNCHRONY WITH THE HEARTBEAT TO PROVIDE CARDIAC ASSIST.

CorInnova has completed three rounds of financing: a 2005 seed round of $500,000 from the State of Texas; a second seed round of $600,000 in December 2014, comprised of various angel investors; and a convertible note round of roughly $7.3m, led by the Wellcome Trust. An additional $5m in convertible notes is scheduled to close by December, targeting existing investors and new high-net-worth individuals and family offices.

"Over the years, we have had continuing discussions with the major medical device companies that are active in the heart failure space or have a significant interest in addressing the heart failure market," Altman said. In fact, the company is headquartered in a Johnson & Johnson JLABS incubator in the Texas Medical Center.

The most likely exit strategy for CorInnova is a sale to a strategic partner or an IPO within the next three years.