

CircuLite Inc.

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Summary: More than 80% of the ventricular assist devices in development today use an open surgical approach. CircuLite Inc. is developing a completely interventional VAD. With its percutaneous device, the company aims to extend treatment to patients at an earlier stage of heart failure, thus halting—or perhaps reversing—disease progression.

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CircuLite Inc.

Minimally invasive, miniaturized ventricular assist for heart failure

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Contact: Paul Southworth, CEO

Industry Segment: Cardiovascular Devices

Business: Interventional VAD for HF

Founded: November 2004

Founder: Accelerated Technologies Inc. (ATI); Paul Spence, MD

Employees: 12

Financing to Date: \$11.3 million

Investors: ATI; Oxford Bioscience Partners; ABN AMRO; Giza Venture Capital

Board of Directors: Richard Geoffrion (ATI); Jeffrey Barnes (Oxford Bioscience Partners); Avi Molcho (Giza Venture); Martien van Osch (ABN AMRO)

Medical Advisor: Daniel Burkhoff, MD, PhD (Columbia University)

It's been five years since **Thoratec Corp.** successfully demonstrated that ventricular assist devices (VAD) can extend the lives of patients with late-stage heart failure (HF), a group with less than a 50% chance of surviving one year. That marked a turning point in the evolution of VADS—which can assume part or all of a heart's pumping function—from a bridge to transplant to an actual destination therapy. Thoratec's success and the reimbursements that followed inspired a new wave of innovation in vascular assist devices with a focus on producing smaller, more powerful and more durable devices that go beyond their predecessors to achieve therapeutic recovery.

Indeed, almost half of all devices in development for HF today are VADS, and in the US alone, VAD sales are expected to increase from \$93 million in 2003 to more than \$600 million in 2008, an annual growth rate of 43%. (See "*Cardiac Assist: A Market Primed for Growth*," Medtech Insight, September 2005.)

Of the 45 ongoing ventricular assist R&D programs, more than 80% are using an open surgical approach. Yet it is because of the high infection rates and other complications of surgical implantation that VADS today remain primarily a bridge-to-transplant therapy for a small percentage of late-stage heart failure patients who have suffered a critical event.

CircuLite Inc. intends to broaden the market by taking VADS out of the surgical suite and placing them in

the hands of interventional cardiologists. The company has developed a miniaturized, partial support ventricular assist device that is delivered percutaneously. With this technology, the company plans to extend treatment to an additional 20% of the chronic HF population—that's a million more people in the US alone. By treating patients at an earlier stage, CircuLite expects to halt disease progression and perhaps reverse its course, giving these patients their first real shot at recovery.

CircuLite was formed in 2004 by **Accelerated Technologies Inc.**, the cardiovascular device accelerator that aligns physicians, investors, and seasoned executives at a very early stage in a start-up's life. (*See "ATI: Is This the Model for Device Development?" IN VIVO, February 2005 [A#2005800043].*) The seasoned executive in CircuLite's case is CEO Paul Southworth, whose long career in the device industry has included executive stints at Becton Dickinson & Co., CR Bard Inc., Braun Corp., and Boston Scientific Corp. Southworth joined CircuLite at its inception and oversees a staff of 12, equally divided between New Jersey and Aachen, Germany.

Cardiac surgeon Paul Spence, MD, of the **University of Louisville School of Medicine** and one of ATI's seven founding physicians, first identified the company's rotary pump technology. It was invented in the mid 1990s at Germany's **Helmholtz Institute**, and the patents on it are owned by European cardiovascular company Medos GMBH, recently acquired by Ventizz Capital Partners. Spence saw in this IP the makings of a long-term implantable miniature VAD. CircuLite has licensed rights to long-term use of the pumping technology and processes from those entities. It has subsequently added new IP, including proprietary control technology and modifications to existing components. In total, six patents have been issued and close to 30 additional have been filed on the company's platform.

The upshot, says Southworth, is an entirely new concept for ventricular assist devices. Because the CircuLite device is designed to supplement, not replace, the heart's function, it is the smallest assist device in development, about the size of an AA battery.

Key to the company's strategy is ease of placement. The CircuLite device in its final form will be implanted percutaneously in the pacemaker pocket near the shoulder. That superficial placement will make it easy for interventionalists to deliver and exchange it. Because the pump will be fully implanted it should carry less risk of infection than first-generation VADS that have components that protrude through the skin. The CircuLite device will connect to a small control unit and battery pack worn on the waist.

Because of its size, the pump will run on minimal energy. The first iteration of the device should last between one and two years; the final version will last up to six. That might span the life of the patient. Or maybe not, says Southworth. If the device proves to be capable of remodeling the heart, he suspects that a large percentage of patients won't require the pump after some period of time.

CircuLite's device is designed to pump two to three liters of blood per minute, about half of the load of a healthy heart. This partial support will allow the heart to retain native function—it will still be pulsatile and capable of increasing output on demand. There is evidence that other heart therapies—stents, pacemakers, and drugs—encourage remodeling, but as of yet there is no definitive large-scale proof that devices such as CircuLite's have that effect. But says Southworth, there is a mounting body of clinical evidence that suggests they do.

If that proves to be the case, as CircuLite hopes, it could open the door to treating earlier-stage patients, NYHA Class III and IV, who have exhausted other device and medical options and have nothing to look forward to but the slim possibility of a full service VAD or a heart transplant.

Southworth says that the device will be less expensive to manufacture than competing technologies, and the ease of implantation will lead to shorter, thus less expensive, procedures. Current, more invasive procedures in which the VAD is placed inside the thorax take up to three hours and the device costs upwards of \$75,000.

Southworth reports that in early sheep studies on CircuLite's technology done at the Helmholtz Institute, procedures took an hour and a half. He believes that CircuLite will be able to shave even more time off that.

Although the company's long-term goal is percutaneous placement, that will not come immediately. The first iteration of the device will be implanted minimally invasively, through two small incisions: the outflow will be connected to the subclavian artery, the inflow via a small right anterior thoracotomy to access the left atrium via Waterson's groove. The second version—the one for CircuLite's IDE submission—will be placed endoscopically into the left atrium. The final commercial version will be percutaneous, with the inflow cannula placed transeptally into the left atrium. Southworth notes that even the minimally invasive first device, implanted through superficial incisions, will carry less risk than any surgical procedures and can be done by interventional cardiologists with surgical assistance.

First-in-man studies of the pump are slated for April 2007 at three European centers, with IDE submission to follow later that year. CircuLite is currently raising funds to cover the first-in-man study. The investors in its \$11.3 million Series A round, ATI stalwarts Oxford Bioscience, ABMN Amro, and Giza Venture Capital, will chip in half of the \$12 million Series B round now in progress. The remainder will come from new investors. Southworth expects the round to close in September.—**Nancy Dvorin**