Vectorious

TEL AVIV, ISRAEL

CONTACT

Oren Goldshtein, CEO

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YEAR FOUNDED

2011

WHO'S BEHIND IT

Oren Goldshtein, CEO, co-founder, has worked in the semiconductor and telecommunications industries; Eyal Orion, MD, co-founder, is CEO of Vascular Graft Solutions; Roni Weinstein, co-founder; Medical director Leor Perl, MD, who is director, Rabin Medical Center Innovation Laboratory

UNMET CLINICAL NEED

In heart failure patient management, clinicians lack tools to tell them whether disease is progressing or treatment is helping patients

SOLUTION

V-LAP, an implantable in-heart digital monitor to measure left atrial pressure, comes with a belt that lets patients send their data up to the cloud for clinicians to review

FUNDING TO DATE

$21 million invested by Broadview Ventures (Boston, MA); RAD Biomed (Israel); GO Capital (China); Cleveland Clinic (Cleveland, OH); Fresenius Medical Care (Germany/USA) and angel investors (Israel)

Heart Failure

VECTORIOUS MEDICAL: GUIDING HEART FAILURE TREATMENT WITH AN IN-HEART LEFT ATRIAL PRESSURE MONITOR

Vectorious is one of several companies offering implantable monitors for heart failure. It's betting that reading left atrial pressure with digital technology will improve treatment decisions and outcomes.

by DEBORAH ERICKSON

Like many start-up companies, **Vectorious Medical Technologies Ltd.** was founded with the specific intent of improving upon a pioneering device and usurping its market share. In this case, however, the heart-monitoring device inspiring Vectorious founders in 2011 was in the midst of a pivotal trial that regulators would not review for another three years. "Back then, we did believe that CardioMEMS [since acquired by **Abbott Laboratories Inc.**] would eventually win approval and pave the way for this new and innovative field. That was our bet," recalls Oren Goldshtein, the CEO of Vectorious and its co-founder, along with Eyal Orion, MD.

For starters, they reasoned that a digital sensor of blood pressure could offer much better signal quality than an analog one built from passive electronic components.

Goldshtein and Orion put their heads together to envision the next stage of implantable hemodynamic monitoring. Goldshtein's own background in the semiconductor/telecommunications industry was a good match with Orion's experience in the medical industry, he points out. Together, they were able to articulate a variety of advances that would be valued by both clinicians and patients dealing with heart failure. For starters, they reasoned that a digital sensor of blood pressure could offer much better signal quality than an analog one built from passive electronic components (like that of CardioMEMS), and that—exactly as has been the case in telecommunications offerings from TV to cable, telephones to personal computing—signal strength and reliability could be leveraged in commercially valuable ways. Similarly, they realized that other technological trends, from the increasing affordability of massive processing power in ever-more-miniature formats, to wireless and leadless capacities, could also help them with their plan.

After obtaining initial funding of $5 million in November 2011, the team began investigating the possibility of creating an in-heart microcomputer by combining certain existing technologies with other novel, proprietary ones. The early investors are from Israel and include Rad-Biomed incubator and experienced high-tech angels. From the very beginning the company understood that in order to build a low-power, miniature and accurate sensory device they needed to develop a proprietary ASIC chip capable of reading the MEMS pressure transducer, processing the data, and transmitting it wirelessly. In the first two years Vectorious worked to establish

proof-of-concept, using discrete electronic components before designing a chip and placing it in a hemocompatible package.

By now, Goldshtein, believes Vectorious has created a device prototype that will improve markedly upon the capabilities of the groundbreaking *CardioMEMS HF System*. The latter was the first FDA-approved diagnostic monitor which was shown to decrease hospital admissions for patients with heart failure, and improve their quality of life.

Vectorious' in-heart microcomputer monitors left atrial pressure directly. Trade-named *V-LAP*, it is implanted via a minimally invasive procedure that begins by inserting a standard 12 French catheter sheath into the femoral vein. Deployment of the sensor device takes about 10 minutes. A septal puncture is performed, and the implant is then pushed through this hole and placed, somewhat like a toggle bolt, with the distal side in the left atrium and the proximal side in the heart's right atrium *(see Figure 1)*. "Nitinol anchors on both sides of the septal wall assure the secure attachment of the sensor," Goldshtein says. With this design, he notes that Vectorious was able to leverage physicians' well established experience with septal occluders and PFO devices.

After the *V-LAP* is put in place, patients each day put on a specially designed belt housing an external unit and press a button to interrogate the implant, process the data, and then transmit it to the cloud using a GSM modem. The upload is complete in under a minute, and the data denoting left atrial pressure is available to clinicians.

Designing *V-LAP* to monitor pressure in the left atrium (on the left side of the heart), as distinct from *CardioMEMS HF*, which measures it in the pulmonary artery (on the right side of the heart), provides a clear differentiation from the competition, Goldshtein notes. By measuring pressure on the left side of the heart, he emphasizes, *V-LAP* takes a direct measurement that is clinically relevant whereas monitoring changes in pulmonary artery pressure obtains only a surrogate measurement of whether the lungs are retaining fluid due to worsening heart failure, Goldshtein asserts. What's more, over 50% of heart failure patients have elevated pulmonary vascular resistance, he says, often because of secondary pulmonary hypertension or COPD (chronic obstructive pulmonary disease), which can lead to "false positives" with respect to worsening heart failure. "Changes in pressure in the pulmonary artery branch don't always correlate with heart failure exacerbations. This is well known," Goldshtein notes. Thus, physicians might prescribe diuretics in response to a high pulmonary arterial pressure reading when the cause is not, in fact, fluid overload due to acute decompensated heart failure.

Figure 1

V-Lap

Source: Vectorious

It's the analog design of the frontrunner's sensor that requires it to be placed in the pulmonary artery branch close to the skin, Goldshtein notes, so that the implanted monitor can communicate with the external unit that records the readings. By contrast, Goldshtein says that Vectorious' digital *V-LAP* monitor can be placed considerably deeper in the heart—up to 30 cm from the surface—and still produce a high resolution waveform. Communication with the digital device is also more robust, according to Goldshtein. For example, if the *V-LAP* detects signal corruption it can retransmit readings. And, unlike an analog monitor, the digital sensor can "send several input channels from the heart, instead of just one," he points out.

In addition to tracking pressure changes, the current prototype monitors temperature and Goldshtein expects future versions to be "able to send additional data acquired from the heart."

Attaching Vectorious' digital monitor to the heart's septum won't impede or block most common transseptal procedures, such as ablation, valve repair, left atrial appendage closure, and septal occluders, Goldshtein says. The device might even serve as a marker useful for guiding clinicians doing other procedures in the heart, he asserts. But the *V-LAP* monitor does occupy the same position as the shunt devices that are emerging as a therapy for heart failure, particularly for patients with the type of heart failure known as HFpEF [Heart Failure with Preserved Ejection Fraction]. (*See "Will Heart Failure be the Next Growth Market in Transcatheter Structural Heart?"* MedTech Strategist, *March 13, 2019.)*

The role for these new shunt devices hasn't yet been defined—developers

of the new implants have yet to provide substantial efficacy data. But even if shunts do become widely used, Goldshtein believes Vectorious is well-positioned. "It would be simple for us to develop a device that is basically a shunt, in which we can imbed our monitor. But it will be very difficult for a shunt company to develop the electronics that can communicate from the sensor to the external wall [of the heart]."

Vectorious has implanted its *V-LAP* device in five humans to date, and Goldshtein says that they are performing well. "Of course we have to do a large efficacy trial, but in terms of function and usability we are already there." The start-up can point to numerous other factors that mitigate the risk of its endeavors, he notes. The key risk reduction, Goldstein avers, is that Vectorious offers a next-generation device in a category for which the regulatory and market pathways have already been established by the CardioMEMS device, which did receive FDA's approval, and by now has some reimbursement in several countries as well as the US. According to Abbott, *CardioMEMS* is on track to get a national coverage decision within two to three years, and "they present very good data on it," Goldshtein says.

Current investors appreciate that the road to market has already been paved by CardioMEMS, Goldstein says, and his start-up intends to follow its plans exactly. Vectorious won't try to prove superiority to the front-runner device, just non-inferiority. To do so, Vectorious will target the same patient population as CardioMEMS did at the outset—Class III heart failure patients—and then, as Abbott is pursuing now, Class II and IV patients as well. Investors are also likely to approve of Vectorious' ability to operate on a "very lean and mean basis" in Israel, and to build and integrate a multi-disciplinary team. Such a stripped-down corporate structure won't suffice going forward, though, because the company wants to build its presence in the US, which has a more advanced infrastructure for remote monitoring, versus Europe, Goldshtein says.

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> ***—Oren Goldshtein***

Now seeking Series C funding, Vectorious already counts among its investors Broadview Ventures from Boston, RAD Biomed of Israel, GO Capital of China, Cleveland Clinic, Fresenius Medical Care and angel investors from Israel.

As more and more large companies look to diversify product offerings with services that help customers, the *V-LAP* digital heart failure monitor allows Vectorious to become part of such service strategies. Few other heart failure diagnostic devices on the market or on the horizon now will be able to be leveraged that way, he argues. "The effectiveness and cost effectiveness of providing services will be all about the specificity of the physiological indication," he declares. If this theory bears out, he predicts devices that monitor only surrogate markers of disease—rather than factors with direct clinical relevance—will not support a service-based strategy.