

V-Wave kicks off enrollment in pivotal study of device for HF

By Liz Hollis, Staff Writer

Israeli startup [V-Wave Ltd.](#) reported the start of enrollment in a study of a minimally invasive device to treat patients with New York Heart Association (NYHA) class III and ambulatory class IV symptomatic heart failure (HF).

The randomized, controlled, double-blinded multicenter Reducing Lung Congestion Symptoms in Advanced Heart Failure (RELIEVE-HF) study (NCT03499236) is assessing the safety and effectiveness of

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V-Wave interatrial shunt; V-Wave Ltd.

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Lungvision launch seen as step towards winning battle against lung cancer

By Ned Stafford, Staff Writer

HAMBURG, Germany – The Israeli lung cancer diagnostics firm [Body Vision Medical Ltd.](#) has launched its Lungvision platform, which is based on technology that the company's founder and CEO describes – in a bold statement – as “a major step towards winning the battle against lung cancer.”

The Lungvision platform will be presented at the annual meeting of the American College of Chest Physicians (CHEST) that begins Oct. 6 in San Antonio and runs through Oct. 10. During

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Datascope warning letter cites supplier, design verification issues

By Mark McCarty, Regulatory Editor

The law of unintended consequences is still at play in the world of cardiopulmonary devices as evidenced by the Sept. 11, warning letter to [Datascope Corp.](#) of Fairfield, N.J. The FDA inspection was driven by a series of adverse events associated with the company's intra-aortic balloon catheters, and the warning letter hit Datascope for its purchasing controls and design verification procedures, which were blamed for leaky catheter balloons and the migration of a lubricant that made surgical use of the device more difficult.

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Neovasc heads for U.S. with Reducer, a minimally invasive angina implant

By Stacy Lawrence, Staff Writer

[Neovasc Inc.](#) is in talks with the U.S. FDA to determine a regulatory path for its Reducer minimally invasive implant to treat refractory angina. That device has been implanted in the first U.S. patient as a compassionate use case, with positive 12-week data. Reducer is already commercialized in Europe and the Middle East, but the Vancouver, British Columbia-based company is now evaluating its next steps to bring the device to the U.S.

Investors were encouraged by the data on the first

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Do drug, device companies meet California's boardroom quota of women?

By Mari Serebrov, Regulatory Editor

If a new California law withstands legal challenges, it will break down the door to the boardroom for women in the drug and device industries – at least for publicly traded companies with headquarters in the state.

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BioWorld MedTech's Orthopedics Extra

Executive Editor Holland Johnson
on one of med-tech's key sectors

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the meeting lung cancer specialists in three separate panel presentations will talk of their clinical experiences using the platform in clinical studies.

The platform consists of the Lungvision imaging and navigation system and the Lungvision tool, which is a disposable navigation catheter. Both products have been cleared by the FDA and, the company says, that the Lungvision platform has accomplished 400 clinical procedures in 12 U.S. lung cancer centers.

Important day for lung patient care worldwide

“This is an important day for us and for all those involved in the lung patient care worldwide,” Body Vision founder and CEO Dorian Averbuch said of Lungvision’s official launch. “Our technology is a major step towards winning the battle against lung cancer. We are targeting small pulmonary nodules that if diagnosed early, can be resected to cure the disease.”

Averbuch told *BioWorld MedTech* that the launch at the CHEST meeting “means that we will be starting to sell our products in the beginning of 2019 to U.S. hospitals.”

In early September, the company reported that it had attracted \$8.5 million in funding from unnamed sources that would be used “to accelerate the commercialization efforts of its FDA approved Lungvision system in the U.S. and to extend its product line.”

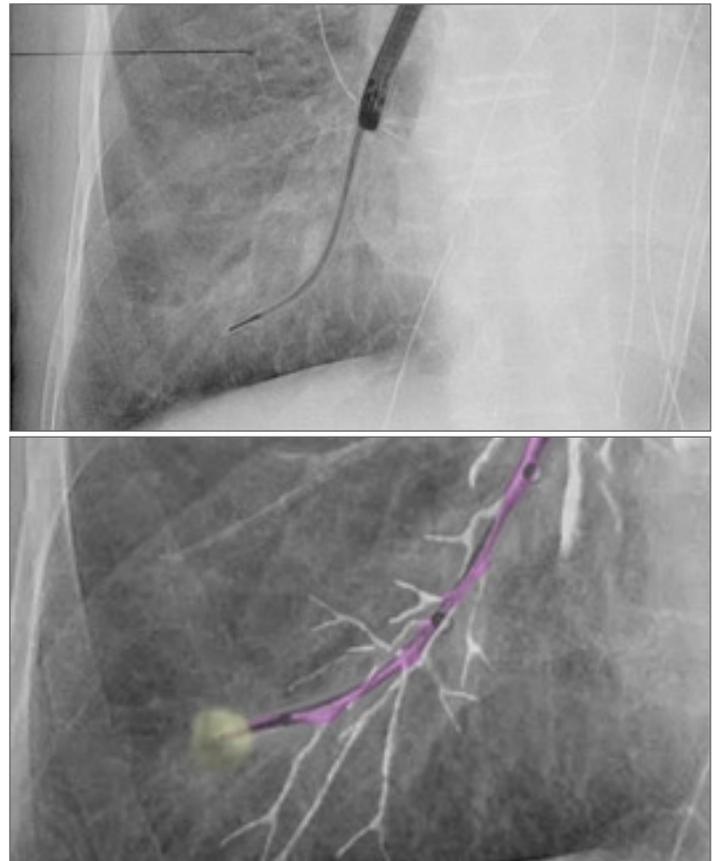
At the time of the funding announcement, Body Vision’s chairman of the board, Zohar Gilon, said that from the very start “we believed that the company was tackling substantial unmet needs utilizing a very novel and very promising approach. Dorian and his world-class team will save a great number of lives, and almost as important, decrease and shorten many families’ pain and suffering.”

Unique technology creates augmented reality

D. Kyle Hogarth, who is president of the Society for Advanced Bronchoscopy and who will give one of the presentations at the CHEST annual meeting, described the Lungvision platform as “a great tool that has changed the way we approached peripheral nodules. Its unique technology creates augmented reality with the ability to see fluoroscopically invisible lesions and the pathways under the live fluoro, while tracking a patient breathing. Once the technology has guided us to the lesion, we confirm the lesion’s relationship to the airway with radial-EBUS.”

“*Our technology is a major step towards winning the battle against lung cancer. We are targeting small pulmonary nodules that if diagnosed early, can be resected to cure the disease.*

Dorian Averbuch
Founder and CEO, Body Vision Medical Ltd.



Blind navigation (top) vs. real-time, 3D visualization with Lungvision (bottom); Body Vision Medical Ltd.

At that point in the procedure, said Hogarth, who is director of bronchoscopy at the University of Chicago, doctors then use off-the-shelf biopsy instruments via the Lungvision catheter. “The augmented fluoro image, integrated with the radial EBUS images, allows us to obtain tissue samples with continuous real-time confirmation of location,” he said. “The beauty of it all is how simple and elegant the technology is.”

Entrepreneur with more than 18 patents

Body Vision Medical, headquartered in Ramat Ha Sharon, Israel, with an office on the Upper East Side in New York City, was founded in 2014 by Averbuch, a medical device entrepreneur with more than 18 patents used in commercial products. He was vice president of R&D at Superdimension Ltd. in the four years preceding its acquisition in 2012 by Covidien plc. (See *BioWorld MedTech*, March 20, 2012.), which was acquired by Dublin-based Medtronic plc in a deal that closed in 2015.

While at Superdimension Averbuch, who holds bachelor’s and master’s degrees in mechanical engineering from the Israel Institute of Technology, learned about interventional pulmonology and the challenges of early-stage lung cancer. He helped develop and commercialize an electromagnetic navigation bronchoscopy approach while working there.

Averbuch and his team at Body Vision saw “the promise of existing electromagnetic systems,” but felt the existing systems

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“provided only a partial solution due to technical limitations, high utilization and maintenance costs, lack of integration with existing technologies and tools, and a long learning curve.” Averbuch believes that the Lungvision platform developed by his company is “a better solution.”

In May 2017, the company received FDA clearance to market the Lungvision imaging and navigation system, which has “capabilities of planning target and pathway for navigation bronchoscopy” for “instant access to early stage nodules.” A year later, in May 2018, the company received FDA clearance for the Lungvision tool to be “used in conjunction with standard bronchoscopes and the Lungvision system to guide endotherapy accessories to small pulmonary nodules.”

Since the founding of Body Vision, Averbuch told *BioWorld MedTech* that the company raised \$10 million in series A funding plus the \$8.5 million in September, which was series B funding. He said the series B round has not yet closed, adding, “we are open to add new investors to the series B round, raising up to \$18 million in total for this round.” ♦

Regulatory front

The U.S. **FDA** said that among its guidance objectives for fiscal 2019 is to finalize the draft guidance pertaining to uncertainty in benefit-risk determinations for PMA, de novo and humanitarian device exemptions. The agency said this item appears on the A list for guidance development for the new fiscal year, which also includes finalized guidances for the special 510(k) program, while the A list for draft guidances includes a guidance for non-binding feedback after device establishment inspections and one for medical device servicing, which will address the differences between reservicing and remanufacturing. On the agency’s B lists are drafts for brain-computer interface devices and 510(k) filings for continuous ventilators, and final guidances for animal studies for organ preservation devices and conformance of X-ray systems with standards published by the International Electrotechnical Commission. A number of existing guidances are up for review at the agency’s device center, including the 1989 final guidance for medical device labeling, the 1999 final guidance for clinical studies of devices for ablation of ventricular tachycardia, and the 2009 final guidance for third-party inspections.

The U.S. **International Trade Commission** said it has received a complaint from Resmed Corp. of San Diego in connection with the import into the U.S. of parts and equipment for sleep-disordered breathing devices that are alleged to be in violation of U.S. patent law. Resmed alleges that Fisher and Paykel Healthcare Inc. of Irvine, Calif., and two of its subsidiaries are infringing on five Resmed patents.

The U.S. **FDA** has extended the comment period for the draft guidance pertaining to refusals to issue certificates for device exports. The comment period is now extended to Nov. 15, 2018, under docket number FDA-2018-D-2310.

The U.S. **Securities and Exchange Commission** said it has for the second time charged **Stryker Corp.** of Kalamazoo, Mich., of violations of the Foreign Corrupt Practices Act, this time for internal accounting controls that did not suffice to detect the risk of improper payments in connection sales of the company’s products in other nations. The agency said Stryker has agreed to settle the charges and pay a penalty of \$7.8 million, and that the company’s subsidiary in India did not maintain complete and accurate books and records. The SEC statement said Stryker did not admit to wrongdoing, and that the company had been charged with FCPA violations in 2013, which resulted in fines, interest and disgorgement in excess of \$13 million.

A package of proposals to respond to the nationwide opioid crisis is on its way to becoming U.S. law. The **Senate** voted 98-1 Wednesday to send the conferenced bill to the president. The White House has indicated that President Donald Trump will sign the bill, which is a consensus of separate House and Senate bills dealing with addiction prevention, treatment, research and enforcement. Included in the final bill are provisions granting the NIH more authority to accelerate research on nonaddictive pain relief and requiring drug and device companies to disclose payments made to nurse practitioners and physician assistants for promotional activities. The lone holdout in the Senate was Sen. Mike Lee (R-Utah), who had opposed the Senate version of the bill last month because of the dozens of new grant programs it would create with little accountability for how the funding would be spent and minimal evaluation of their effectiveness. The House passed the bill late last week. (See *BioWorld MedTech*, Sept. 19, 2018.)

Product briefs

Boston-based **Ag Mednet Inc.** reported it is delivering its Judi // Imaging services to **Qynapse SAS**, of Paris, to ensure accurate deployment of medical images within Qynapse’s quantitative imaging services for clinical trials. Judi // Imaging provides the functionality and support needed to collect image data, de-identify it to ensure regulatory compliance, apply automated quality-assurance processes, and deliver it reliably and securely to trial repositories. Qynapse provides a cloud-based solution for pharmaceutical companies and health care providers to support the accurate diagnosis, prognosis and drug efficacy measurement for central nervous system diseases.

Carbofix Orthopedics LLC, of Herzeliya, Israel, said the U.S. FDA cleared its Carboclear carbon fiber transverse connectors to be used in conjunction with its carbon fiber pedicle screw system, which was cleared by the FDA earlier this year, to surgically treat oncological patients.

Fziomed Inc., of San Luis Obispo, Calif., said its Oxiplex/IU adhesion barrier gel for intrauterine surgery is CE marked and available in the EU. It is an absorbable, synthetic viscoelastic gel that is applied following intrauterine surgery to preserve uterine integrity and improve surgical outcomes by reducing postsurgical adhesions.