

Medical device in a new vein may soon treat hypertension

By **THOMAS LEE**, Star Tribune

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After eight years and more than \$200 million in venture capital funding, CVRx Inc. is near the homestretch of its quest to sell the first implantable device that treats hypertension, or high blood pressure.

The Brooklyn Park-based company will announce today that it raised \$84 million in new financing, money that will fund the Phase III clinical trials of CVRx's technology, called the Rheos System, in the United States. Phase III is the last stage of testing before the Food and Drug Administration decides whether to approve the device.

The latest round of financing was led by New Enterprise Associates and Johnson & Johnson Development Corp. Other investors included BBT Fund, Thomas Weisel Healthcare Venture Partners, InterWest Partners, Frazier Healthcare Ventures and SightLine Partners.

But CVRx executives are already looking beyond blood pressure: Part of the \$84 million will be used to conduct research into whether Rheos can also treat heart failure. They also think that Rheos could replace hypertension drugs altogether, but that would require further study.

Rheos "really does show a lot of promise in multiple disease areas, and with this new financing in place we really have a tremendous opportunity to help the product to realize that potential," said CVRx founder and chief technology officer Robert Kieval. "As exciting as it has been to get to this point, the future is going to be every bit as exciting and fulfilling."

There are skeptics

However, one expert says Rheos requires invasive surgery and may only benefit a tiny percentage of the 73 million Americans with hypertension. There are more than 100 medications, including inexpensive generic drugs, that effectively treat the condition, said Kevin Graham, director of preventive cardiology for the Minneapolis Heart Institute at Abbott Northwestern Hospital.

Here's how Rheos works: A device implanted beneath the collarbone sends electrical pulses to the carotid arteries, which then send signals known as baroreceptors to the brain.

The baroreceptors tell the brain that the body's blood pressure is too high. In response,

the brain instructs organs such as the heart and kidneys to expand blood vessels and stop producing stress-inducing hormones.

"We haven't discovered or created new physiology," Kieval said. "We found a new way to exploit that physiology with modern medical technology. These are pathways [that the] brain is [already] expecting information from. What we are doing is augmenting that information."

CVRx recently released two years of data from a study in Europe that showed patients using Rheos showed a sustained drop in blood pressure. European regulators have already approved Rheos for commercial use. The company is currently enrolling 300 patients at 50 sites across the U.S. for the Phase III trials.

Finding suitable patients

The biggest challenge facing CVRx is identifying which patients would benefit from Rheos and persuading skeptical doctors to recommend an invasive surgery over drugs, said Ross Meisner, managing director of Dymedex Consulting in St. Paul who is not affiliated with CVRx.

Graham, of the Minneapolis Heart Institute, is one of those skeptics. While the company estimates about 25 percent of people with high blood pressure could benefit from Rheos (patients with severe hypertension that doesn't respond to medication), Graham puts that number closer to 1 percent. Rheos seems to work but should only be used as a last option, he said.

"You don't put a pacemaker in someone unless you really need to," Graham said.

Like a pacemaker, Rheos' battery life is finite and will likely need to be replaced, requiring more surgery. Plus, doctors don't yet know the device's long-term effects on the body, he said.

While CVRx is testing Rheos in combination with drugs, CEO Nadim Yared says the technology could reduce or even eliminate pharmaceuticals altogether. Drugs are often ineffective because patients frequently don't adhere to their therapy, he said.

"Compliance is very low," Yared said. "Patients hate taking their pills."

Said Kieval: "We don't believe that drugs are required for Rheos to have the efficacy that it does. That is something we will have to prove in clinical trials."

People who are interested in enrolling in the Rheos clinical trials can go to www.bloodpressuretrial.com or call 1-888-8BP-Risk (888-827-7475).

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