



VentureWire Alert

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VCs Eyeing New Treatments For 'Silent Killer'

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Some venture capitalists are taking aim at one of America's top killers.

Each year, roughly 15,000 Americans die from the rupture of an abdominal aortic aneurysm, a bulge that forms in the main artery leading from the heart. That makes these aneurysms, known as AAAs, the 13th leading cause of death in the U.S., according to the American College of Cardiology. Conventional treatment calls for abdominal surgery, which is effective but invasive.

In the 1990s, venture firms funded start-ups AneuRx Inc. and TriVascular Inc. to develop endovascular treatments, which require only small incisions. Medtronic Inc. acquired AneuRx in 1996, while Boston Scientific Corp. bought TriVascular in 2005.

Now, some former AneuRx and TriVascular executives aim for a second score. In March, TriVascular investor Delphi Ventures helped spin the company out of Boston Scientific. Meanwhile, AneuRx co-founders Michael Evans and Gwen Watanabe lead a rival, Nellix Inc., whose backers include Essex Woodlands Health Ventures. Both must contend with Aptus Endosystems Inc., a 6-year-old company funded by U.S. Venture Partners, among others.

Competition is rising along with demand for endovascular therapy -- introduced in 1999 -- which promises a faster recovery with less pain. Today, these treatments account for about 70% of AAA procedures at major metropolitan hospitals, according to Aptus Chief Executive Bob H. Katz. Aptus, Nellix and TriVascular2 Inc. aim to improve upon devices made by competitors, such as Medtronic and Cook Group Inc., by developing new tools that enable even better results.

As technology improves and the population ages, the market for endovascular AAA remedies will likely expand even further. Today's \$390 million U.S. market will balloon to \$620 million by 2012, predicts Millennium Research Group. With that growth, "there is significant room for additional players," said Evans, founder and president of Nellix.

Shortened Recovery Times

Since they usually cause no symptoms, AAAs are sometimes known as "silent killers." Most are discovered during imaging exams done for other reasons. Their cause is unclear, but smoking, aging, atherosclerosis, and other factors are thought to weaken the aortic vessel wall and permit a balloon-like sack to form. As an aneurysm grows, so does the likelihood that it will burst and cause internal bleeding.

The traditional remedy is "open" surgery, in which surgeons cut into the abdomen and replace the diseased portion of the aorta with a tube, or graft. It requires four to seven days in the hospital, and recovery takes six weeks or more. With the endovascular alternative, physicians make small incisions in the groin and feed a stent graft up through the femoral artery to the aneurysm. The hospital stay is one or two days, and patients resume normal activity in a week.

Patrick Clagett, a surgeon at University of Texas Southwestern Medical Center, said 80% of his patients choose endovascular repair when given the choice because it's easier to take. Short-term results support this choice. An analysis of 45,660 open and endovascular cases published in the New England Journal of Medicine in January found the death rate within 30 days of treatment was four times higher for open surgery, 4.8%, than for endovascular therapy, 1.2%.

Today's endo-grafts may shift, or migrate, in the body from their intended position over time, however. Because of this and other complications, 20% to 30% of endovascular-treated patients need re-treatment within 10 years, according to David C. Brewster, a surgeon at Massachusetts General Hospital. By contrast, the open-surgery re-treatment rate within the same period is about 5%, he said.

Most re-treatments for endovascular patients are relatively minor. Still, a re-intervention rate of 20% "is not a number to be proud of," said Nellix's Evans, whose company has technology to anchor its graft in place to prevent migration, though the Palo Alto, Calif., company is keeping most details about its approach and operations to itself.

New companies also eye other technical improvements, including systems that make it easier to gain access to the aorta through femoral and iliac arteries. Three years ago Boston Scientific paid about \$60 million cash, plus milestones, to acquire a company with such a technology, TriVascular. The corporation, however, discontinued work on TriVascular's device shortly after completing its 2006 merger with Guidant Corp. Since then, it has been shedding non-core assets, creating opportunity for Delphi, New Enterprise Associates, MPM Capital and Kearny Venture Partners to spin TriVascular2 out with a \$65 million financing.

The spinoff of the Santa Rosa, Calif., company, and its CEO, Michael Chobotov, enables it to restart work on its system, expected to enter clinical trials in the U.S. and elsewhere in 2009.

Plans for a 2010 U.S. Launch

Nellix and TriVascular are not quite as far along as Aptus Endosystems, of Sunnyvale, Calif., which aims to make endovascular therapy as durable as open surgery. Its system includes "EndoStaples" to secure its graft. "It is as strong in bench models as a surgically sutured attachment," said CEO Katz.

Aptus, now conducting a pivotal study, called STAPLE-2, announced positive results from its STAPLE-1 study in June. No migration was found and no endoleaks -- the leakage of blood outside the graft -- were observed in patients out to one year. If it sees similar results in STAPLE-2 it could launch in the U.S. in late 2010.

"We'll be the first one to compete with current, entrenched competitors, and based on our clinical data, we think we'll do very well," said Alan Kaganov, a partner of USVP.

Competitors include Cook Group, Endologix Inc., W.L. Gore & Associates Inc. and Medtronic, which acquired AneuRx -- for about \$72.5 million in stock -- before the start-up had begun human studies. These days, buyers are waiting for a start-up to secure regulatory clearance, so Nellix and TriVascular2, like Aptus, must be prepared to drive their products to market.

Not every investor behind the first wave of companies wants back in. Mark Wan, a partner at former AneuRx-backer Three Arch Partners, said he hasn't seen a new technology that he considers to be a significant leap. "It's been hard to identify a clear, superior solution," Wan said. "We haven't seen that approach that has been compelling to us."

Whether these upstarts will trump the current leaders remains to be seen, of course, but some argue that there will be room for several players.

Two hundred thousand AAAs are diagnosed in the U.S. each year, according to the Society for Vascular Surgery, but experts say thousands more remain undetected. The Screening Abdominal Aortic Aneurysms Very Efficiently act, in effect since January 2007, provides coverage for screening of high-risk Medicare

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beneficiaries.

This could increase the number of AAAs diagnosed and boost the market opportunity, as could growing interest in endovascular treatment of thoracic aortic aneurysms, a nascent sector that Aptus, Nellix and TriVascular2 are eyeing as well.

As the number of patients seeking endovascular aneurysm repair grows, so will demand for new treatment options. As a result, "There is still an opportunity for product entry," said MPM Capital Managing Director Jim Scopa.