

Tissue Engineering Start-Up Cytograft Raising \$15M Series A

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Novato, Calif. -- Cytograft Tissue Engineering Inc., which is developing "sheet-based" tissue engineering technology designed to create blood vessels from a patient's own cells, is raising \$15 million in Series A capital. It is the company's first institutional round and is expected to be a precursor to a \$50 million Series B round in the coming years.

Cytograft will likely close on the Series A round by June 2006, said co-founder, President and Chief Executive Todd McAllister. He said the \$15 million would sustain the 10-employee company for about three years and would be used to carry the company through several clinical trials in the U.S. and abroad.

At that point, McAllister expects have demonstrated efficacy in several trials. Cytograft will then require another investment in the vicinity of \$50 million to address manufacturing and scale-up issues, he said. With trials underway in Argentina and on the radar for Europe and perhaps Asia as well, Cytograft plans to initiate U.S. trials next year. The company expects to submit an investigational new device application in March 2006 and to start enrollment in June. McAllister expects to have modest sales in Europe by the beginning of 2007 and in the following year in the U.S.

The Novato, Calif.-based Cytograft has previously received \$5 million in seed financing from Saratoga Ventures LP and individual investors, as well as \$2.5 million in grants from the National Institutes of Health.

"We have been very focused on this application of the blood vessel itself on a very, very minimalistic research budget," McAllister said. He compared Cytograft to companies such as Sunrise, Fla.-based cardiac therapy company Bioheart Inc. and Osiris Therapeutics Inc., a Baltimore-based developer of adult stem cell-based therapeutics. Those two companies have raised far more capital - post-money valuation of their most recent rounds was \$67.5 million and about \$250 million respectively - and are at roughly the same stage of development. "From our perspective, we will make [venture investors] sit up and say, 'Holy cow,'" he said of the company's capital-efficient business model.

Cytograft's sheet-based tissue engineering technology, Lifeline, requires a small dermal biopsy from which fibroblast cells are extracted. The company is then "able to grow those cells in sheets and to take those sheets and shape [them] into vessels with enough robustness to replicate a normal vessel - maybe even stronger," said Rich Ferrari, managing director at De Novo Ventures and a Cytograft director. Though Ferrari sits on Cytograft's board, De Novo is not an investor in the company.

Instead of trying to rebuild the exact structure of an artery, Cytograft ultimately decided to exclude smooth muscle cells, McAllister said. This was motivated by two factors: It is simpler from a manufacturing/production process, and smooth muscle is associated with the primary failure mode - intimal hyperplasia - and that is the primary mechanism of restenosis, or the reclosure of a blood vessel following a graft.

Cytograft is targeting four applications: an arteriovenous, or AV, shunt for hemodialysis patients; a peripheral graft for limb salvage in patients that have critical limb ischemia and who are targets for amputation; a coronary graft for coronary bypass candidates; and

pediatric applications for the repair of congenital defects. The vessel-growing process requires about six to nine months.

Cytograft's primary concentration is the use of a Lifeline graft as an AV shunt for hemodialysis patients that would otherwise receive a synthetic expanded polytetrafluoroethylene, or ePTFE, shunt. Cytograft's challenge is to develop something similar to the native vein. "[A patient] is not going to pay \$25,000 for a blood vessel if a \$2,000 piece of plastic works just as well," McAllister said.

What is unique about Cytograft's material is that it is completely autologous - derived from a patient's own cells - and therefore does not use any synthetic materials the body may recognize as foreign. According to McAllister, Cytograft's advantages include pressure from the National Kidney Foundation and Medicare/Medicaid to find alternatives to the plastic grafts as well as a favorable European regulatory environment for completely autologous products.

The company has approval for two clinical trials and is conducting studies in Argentina for its initial application. Enrollment was initiated 18 months ago and Cytograft has brought on nine patients. Cytograft also has approval for a second trial in the U.K. in CABG for up to 25 patients.

The company has also recently submitted an application to regulatory authorities in Argentina to initiate a study in revascularizing the lower limb and McAllister said Cytograft is meeting with an investigator in Japan in a few weeks to discuss using Cytograft's tissue in his pediatric patients.

The company's other co-founder, Nicolas L'Heureux, invented the technology of sheet-based tissue engineering at Quebec-based Universite Laval about 15 years ago. After founding the company in 2000, L'Heureux and McAllister have spent the last five years developing the technology.

<http://www.cytograft.com>

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