

minnesota BUSINESS

INSPIRATION FOR GROWING COMPANIES

THE (REAL) POWER 50

▶ **SMART MOVE:** Lab testing is faster and cheaper than a clinical trial.

Doug Killion shows off a clean room where the device is made

Med device on fast track

Pursuit Vascular's ClearGuard HD antimicrobial device for kidney catheters to be launched this year **BY DAN EMERSON**

For early-stage medical device companies, the path to regulatory approval and commercialization is typically long and expensive. But Maple Grove-based Pursuit Vascular has enjoyed at least one advantage in its quest to market its technology, which reduces catheter infections in kidney dialysis and other patients.

The product is a polymer rod coated with a dry, antimicrobial agent that kills bacteria inside a catheter, reducing infections by about 75 percent. The ability to prove ClearGuard's effectiveness in lab testing, rather than a clinical setting, helped Pursuit gain relatively rapid approval by the FDA. The company was able to avoid the considerable expense of clinical trials to prove the product's ability to kill bacteria, fungi, and other microorganisms.

LOCAL ANGELS

As a result, "our company is a little unique in the medical device space," says CEO and president, Doug Killion. Unlike most early-stage device firms, "we don't need tens of millions of dollars, and we have been largely financed by angel investors, mostly in the Twin Cities.

We're fortunate in this area to have the Twin Cities Angels and Gopher Angels to help speed the process along."

Pursuit has also used the Minnesota Angel Tax Credit as a tool in raising \$4 million on its financing, which returned 25 percent to those investors.

Pursuit's relatively modest fundraising needs have also presented a challenge, in that they are not large enough to interest traditional venture capital firms, Killion says. Even a smaller VC firm typically seeks to make investments of \$8 million to \$10 million in each of its portfolio companies. "So, we're in that in-between zone."

Still, the company was able to meet its Series B goal of \$5 million, closing the round on March 20 with commitments from several angel investors. With a product launch planned for later this year, Pursuit will use the \$5 million to support customer product evaluations and expand manufacturing capacity.

UNIQUE DEVICE

The U.S. Food and Drug Administra-

tion approved Pursuit's ClearGuard HD device for marketing in December 2013. It was the first of a planned series of products based on Pursuit's patented technology.

The device prompted the creation of a new product code by the FDA, because Pursuit's device is the only one in its category, according to Killion. The product is already being used and evaluated by the two largest dialysis providers in the U.S., who control 70 percent of the market.

Pursuit's technology was developed by researcher Robert Ziebol, now the company's vice president of R&D. "Bob had spent 25 years in the (infection control) space and knew the struggles related to hemodialysis (HD) catheters, which are very prone to infection," Killion says.

Others had tried injecting antimicrobial liquids into HD catheters, but none of those products were able to win FDA approval due to safety concerns. Ziebol came up with the idea of attaching a rod coated with an antimicrobial agent to the catheters. "It provides the efficacy of a liquid without the safety risk," Killion says. In 2011, Pursuit won a Tekne Award from the Minnesota High-Tech Association.

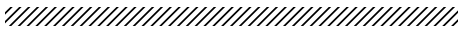
One of Pursuit Vascular's patented ClearGuard products



ABOVE: BY JOEL SCHNELL; BELOW: SUBMITTED BY PURSUIT VASCULAR



BIZ BRIEFING



PURSUIT VASCULAR

HEADQUARTERS: Maple Grove

INCEPTION: 2009

LEADERSHIP: Doug Killion, President and CEO; Robert Ziebol, vice president of R&D and co-founder; Nancy Ness, treasurer and CFO.

EMPLOYEES: 8

REVENUE: Not disclosed

DESCRIPTION: Designs and manufactures ClearGuard HD antimicrobial device for catheters.

WEB: pursuitvascular.com


“You also need to understand how the Medicare payment model is changing,” Killion says. “In one respect, they are passing the cost of infections back to the provider of outpatient dialysis services.” Pursuit has used specialized consultants who conduct detailed analysis of the dollars and cents costs of infections, using data on hundreds of thousands of dialysis procedures.

COUNTDOWN TO LAUNCH

Last year, Pursuit moved into a new lab and manufacturing facility in Maple Grove, equipped with a custom-built clean room. The patented manufacturing process is done in-house. “We’ve been making tens of thousands of devices every month for use in evaluations with our key customers,” Killion says.

Pursuit has also solicited feedback from nurses, physicians and technicians, and used those insights in refining the product.

The starting point for developing a successful medical-device technology is “a strong, unmet need,” says Killion. “Providers and insurers have been desperately looking for a solution for their catheter patients, and that’s what this product represents.”

The potential market is huge. According to the Centers for Disease Control, one of today’s top seven health care challenges is catheter-related bloodstream infections. The infections cause about 30,000 deaths and increase U.S. health care costs an estimated \$6 billion each year. And the single biggest sector of these infections are kidney-related, the target application for ClearGuard. 

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