Five Questions with Bill Niland, Harpoon Medical CEO

By: Scott Dance, The Baltimore Sun

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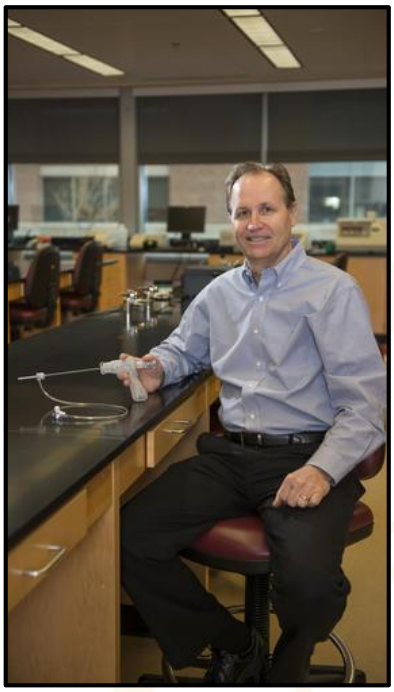
Within a year and a half of launching as a startup, Harpoon Medical's heart surgery device could be used on humans for the first time in a matter of weeks.



Bill Niland, CEO of Harpoon Medical

The Kent Island-based company expects doctors in Poland to employ it by the end of the year or early in 2015. The device is a tool for minimally invasive surgeries to repair the heart's mitral valve, developed by a doctor at the University of Maryland Medical Center.

It would cap a busy 2014 for Harpoon, during which CEO Bill Niland raised millions of dollars in investment, and at the end of which the company plans to move to new headquarters in the warehouse building at Camden Yards.

Here's what Niland, who previously founded medical device company Vapotherm in Stevensville, had to say about the progress and what's ahead.

It's been a busy year. How has it gone?

So far it's gone as planned. We incorporated the business in July of 2013, and in the first six months we raised $900,000 just to be able to start hiring and to do animal work, upgrade the device and such. Then back in January we decided to freeze the product design to get it ready for manufacturing. And most of my time was spent in the first part of 2014 lining up investors for the round we did in the summer. In August we closed a $3.6 million round. We have continued to do more animal work and moved toward what we call our early efficacy trials, which are your first human trials. The plan is to get those first human trials done in 2014.

What is it like looking for investment these days?

In my previous two companies, I raised about $35 million in venture money. The market is definitely different than when I raised venture money before. The venture companies want you

to be further along. They don't want to invest in early-stage companies, which we were considered early-stage. Anything prior to regulatory approval they consider early-stage.

Most venture capital companies would like to see you through your early stage, through the regulatory process and some even into revenue. They're definitely not taking as much risk now, especially in the medical market. We were able to attract some angel investment, and Epidarex Capital and the Maryland Venture Fund and the Abell Foundation all together stepped up and led this round. … We did have some angel investors that came from Texas and a cardiologist in China who invested in this round. But our angel investors were, a large percentage, from Maryland. We already have to start raising our second round. Our goal is to have that money raised by next May.

What are the next milestones you're looking to hit?

The milestone is, between now and March, to do our early efficacy trials, called early feasibility studies. We are contracted with a site in Poland that we'll be doing our early feasibility trials at. From there it'll go into what we call our CE trial, the regulatory approval for Europe, next year in probably three different countries in Europe. Our goal is to have that trial completed by 2015 and have our CE regulatory approval by the middle of 2016. That would be when we would be first commercially available.

The goal now is to get really good clinical data and prove that this works very well. The U.S. is going to be a little bit longer. Right now we're targeting late 2017 for FDA approval. We've started to meet with some FDA consultants in this area and probably looking at our different pathways to U.S. approval. We're probably looking at, as we finish up the CE trial at the end of 2015 and during 2016 we expect to start any testing we need to do in the U.S., probably in the second half of 2016. Sometimes they'll take your European test, but still want to see you do a smaller study in the U.S. It just depends how that goes.

How are you using the investment?

The B-round of funding would cover the CE trial and the start of commercialization in Europe. The Series A was covering the early feasibility trials — early feasibility and finishing our animal work — and also new research and development. We always want to strive to be minimally invasive. We now need an inch-and-a-half to a 2-inch incision. Our goal is to get that down to a half-an-inch incision. Smaller and smaller is what we want to strive to get. We want to do the procedure on a beating heart and potentially go home in two days, and back to work in 10 days.

What is similar or different about leading Harpoon compared to other companies you've led?

At Vapotherm, it was pretty much a clear cut. We started off in the U.S. with Vapotherm, and we didn't have to go to Europe. We didn't get European approval until two years later. The U.S. market is the big market and what everyone wants to see you in, but the regulatory process does make it easier to go to Europe first for the type of device we're developing. This is more difficult because it's considered a Class 3 device, because we are going into the heart. The FDA puts a Class 3 on that, their highest level of classification, which makes it more difficult to obtain regulatory approval to sell. We've hired a great regulatory person and regulatory experts that are going to guide us down that path.

Also, this device is developed by Dr. Jim Gammie, the chief of cardiac surgery at University of Maryland. Jim is the world [mitral valve] expert. We license the technology from the University of Maryland and Jim is a big part of our company. From the technology and clinical side, it's basically Jim's dream, it's his product. I'm just kind of driving the ship, but this is really Jim's baby.

Bill Niland

Title: CEO, Harpoon Medical

Age: 57

Residence: Arnold

Birthplace: Buffalo, N.Y.

Education: Bachelor's degree from Rowan University

Family: Wife, Kim; two adult sons

Hobbies: Boating, sailing and cycling

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