

## Medical Device Technology for Minimally Invasive, Beating Heart, Mitral Valve Repair



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**CEOCFO: Mr. Boyd, what is Harpoon Medical?**

**Mr. Boyd:** We are a medical device company that is developing technology for minimally invasive, beating heart, mitral valve repair. We are trying to take a disease state that is currently treated almost exclusively with open-heart surgery while the heart is stopped and do it with a small incision between the ribs while the heart continues to beat.

**CEOCFO: What have you found out so far that leads you to believe it can be done?**

**Mr. Boyd:** The idea was developed by Dr. James Gammie, MD, who is the Chief of Cardiac Surgery at University of Maryland. He does over 200 mitral valve operations a year. He spent a lot of time thinking about how he could develop a better procedure for his patients. That started with bench work in the lab that was supported by grant funding and then subsequently, animal studies. More recently the company completed an early feasibility study in Europe. To date, we have operated on ten patients with very good initial clinical results.

**CEOCFO: When might a patient be appropriate for this procedure or for your version of the procedure?**

**Mr. Boyd:** There are two different types of mitral valve disease. One is referred to as degenerative mitral valve disease and the other is functional. The first iteration of our device is focused on patients with degenerative mitral valve disease. It is well established in the clinical literature that when those patients have severe mitral regurgitation, which occurs when the mitral valve does not close properly, and instead of all of blood flowing out through the aorta into the body, some of it goes backwards into the left atrium. The flow of blood backwards into the left atrium is known as mitral valve regurgitation. When that happens, mitral regurgitation is scored from none, if the person has a normal valve, through mild to moderate to severe. It is well established that patients with severe degenerative mitral disease or regurgitation, should have their valve repaired.

**CEOCFO: We know this in advance? It is not a sudden occurrence?**

**Mr. Boyd:** That is exactly correct. For the degenerative portion of the disease, it is a progressive process. It is generally identified through a normal checkup. If your doctor says you have a heart murmur that is oftentimes because you have some amount of regurgitation. They can use echocardiography to assess how much regurgitation you have. Over time with degenerative disease, it gets worse. When it gets to the level where you have severe disease, those patients should be referred to surgery especially if they have other symptoms such as shortness of breath, lightheadedness or anything like that.

**CEOCFO: How does the procedure work and what is the instrument you have developed?**

**Mr. Boyd:** Essentially what we have done is come up with an innovative way to wrap a suture around a needle so that you can pierce the valve tissue and form an anchor on the digital side, the back side. For simplicity sake, it looks a little like a gun. We have created a gun shaped instrument that allows a surgeon to make a small, 1 to 2 inch incision between the patient's ribs and place a temporary valve outside of the heart. The device is inserted through the valve and navigated under image guidance until the device is in contact with the leaflet. Then the surgeon presses a button, the needle shoots out, pierces the leaflet and ties a knot on the backside of the leaflet. From there, you can remove the device and this ePTFE suture will be trailing out of the heart. The surgeon can implant multiple ePTFE neochords and use the chords to pull the leaflet back into its proper positioning.

**CEOCFO: *What were the biggest challenges in creating the device?***

**Mr. Boyd:** Dr. Gammie does this procedure if not every day, certainly every week in open-heart surgery where he stops the heart, cuts it open and can see what is going on as he stitches the suture into place. He was looking for a way to do that without stopping the heart and cutting it open while the heart is beating. It turns out that attaching a suture to a beating heart is much harder than you might think. He and an engineering team went through probably ten to twenty different iterations of the device in his research lab before we finalized the current design and moved it into the clinic.

**CEOCFO: *Where are you today?***

**Mr. Boyd:** We formed the company a little over two years ago. In early October, Dr. Gammie presented the results on our first ten patients. The company raised \$4.5 million in a Series A round in August of 2014. Our Series A investors invested another \$2 million last month (September of 2015) in convertible debt. We are in the process of raising a \$10 to \$12 million Series B round to finance a larger clinical study in Europe that will be required for European approval and commercialization.

“The mitral market is the next growth market in the medical device space. There is a great deal of interest amongst both surgeons and the larger companies in the space. In the last six months, there have been four acquisitions of startups like ourselves for anywhere from \$250 to \$800 million. Harpoon has developed a device that will dramatically improve the treatment of mitral valve disease and has very promising preliminary clinical data on par with those companies but we were able to get there for less than \$5 million.” - Peter Boyd

**CEOCFO: *How many of these procedures are done annually?***

**Mr. Boyd:** It depends on how you look at the market opportunity but it is pretty well established that there are approximately four million patients in the United States with severe mitral valve regurgitation and forty to fifty percent of those patients have degenerative mitral valve disease if not more. That is the type of patient that we are initially focused on. We feel like there are at least a million patients who would benefit from our therapy. That is kind of a top down analysis of the market. There is approximately the same number or slightly more in addressable markets in Europe. If you look at patients who are being treated today, they are somewhere between fifty and sixty thousand mitral valve operations in the United States a year and another fifty to sixty thousand in addressable markets in Europe. It is a very big market and much of it has to do with the underserved patients who are not currently being referred for therapy, either because of the invasiveness of the surgery or because they elect not to have a procedure. That is where there is a lot of opportunity for us.

**CEOCFO: *Have cardiac surgeons been looking for a better method? Is this something that is on the radar screen for most of the practitioners who would make use of it?***

**Mr. Boyd:** Yes. An analogy would be the aortic valve. You have two valves on the left side of your heart. One is your mitral valve and the other is your aorta valve. About a decade ago, people figured out how to replace the aortic valve while the heart is beating. That is probably the fastest growing medical device market ever. That market has gone from zero to over two billion in less than a decade. The mitral valve market is estimated to be three to four times larger. When we go to conferences, the sessions on minimally invasive mitral valve repair are packed. Last week at the TCT conference, it was standing room only for the mitral valve session.

**CEOCFO: *What surprised you through the process? What were some challenges as you have gone along?***

**Mr. Boyd:** In terms of challenges, it is still surprising how challenging the early fundraising marketplace is for high risk, highly innovative medical device companies. We have been lucky. Dr. Gammie is a key opinion leader in this space because he is one of the best mitral valve surgeons in the world. Our president and CEO Bill Niland, this is his fourth healthcare related startup. Even for us, with innovative technology and a really strong team, it was harder than we might have anticipated to raise those initial funds. We kind of knew the climate was challenging when we started and it was potentially more challenging than we had anticipated but I think we have gotten past that early stage and are beyond that now.

**CEOCFO: *Why pay attention to Harpoon Medical today?***

**Mr. Boyd:** The mitral market is the next growth market in the medical device space. There is a great deal of interest amongst both surgeons and the larger companies in the space. In the last six months, there have been four acquisitions of startups like ourselves for anywhere from \$250 to \$800 million. Harpoon has developed a device that will dramatically improve the treatment of mitral valve disease and has very promising preliminary clinical data on par with those companies but we were able to get there for less than \$5 million.