



Q&A with Charles Laverty, CEO Advanced Bifurcation Systems bringing to market their Dedicated and Main Branch Stent Technology for Bifurcation Lesions in Coronary Angioplasties



Charles Laverty
Chief Executive Officer

Advanced Bifurcation Systems
www.advancedbifurcation.com

Contact:
Betsy Brod
212-661-2231
betsy.brod@mbsvalue.com

Interview conducted by:
Lynn Fosse, Senior Editor
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CEOCFO: *Mr. Laverty, what have you developed at Advanced Bifurcation systems?*

Mr. Laverty: We have developed innovative technology for bifurcation lesions in coronary angioplasties, a large unmet need today. In the left main artery, there are branches like branches coming out of a tree. When plaque builds up in the main artery, physicians put stents in to open the artery and allow blood flow. The problem is that you have the same plaque in the branches as well. Today, there is no real solution for addressing the plaque buildup in the side branches. There have been many companies that have tried to develop something for bifurcation for the past twenty years with about two billion dollars spent and it has not yet been perfected. The chief scientist and one of the founders of ABS is a man named Henry Bourang. Henry is an engineer and a scientist who started his career about thirty years ago. He was instrumental in some of the first stents coming to the marketplace. He worked at Edward's Laboratories, Abbot, Boston Scientific and a company called AST, which was acquired by Boston Scientific. Henry was always perplexed with this bifurcation problem. He met a physician named Mehran Khorsandi, an interventional cardiologist from Cedars-Sinai Hospital in Los Angeles, California and they started looking at this problem together about eight years ago.

CEOCFO: *What have they created at this point?*

Mr. Laverty: They created what is called a mother daughter stent. In other words, they created an opportunity to use a single wire with a wire on top. This goes into the branch first, and then the main artery. Today, physicians have makeshift procedures which often create additional problems post-surgery like restenosis and thrombosis.

CEOCFO: *Why has it been so difficult to create something to overcome the problem?*

Mr. Laverty: This is a potentially complex medical condition that today can only be done by the most capable interventional cardiologists and even then, because of the technique involved, the patient can experience restenosis or thrombosis. We have developed a proprietary, patented process that takes much less time to perform and can be done by most interventional cardiologists, not just at large medical centers with highly skilled professionals. We currently have thirty-five patents issued on this process. We have eleven in the US, seven in Australia, six in China, eight in Europe, two in Japan, and one in Canada. There are ten additional patents pending and we expect to shortly have forty-five patents on the process. I might add that when physicians are trying to do bifurcations today, it takes them about an hour to an hour and a half and they end up sending the patient to open heart surgery. With the ABS platform, you can do the procedure in about fifteen minutes.

CEOCFO: Are there different systems depending on the exact point that this is needed?

Mr. Laverty: There are not really different systems, but there are different sizes depending upon the patient and their size. There are different sizes of stents and catheters which you would use to do the process.

CEOCFO: Where are you today in development?

Mr. Laverty: There are two different stents in the market today, bare metal and drug-eluting which is about 80% of the market. Henry and Moran developed the process before I joined, but they wanted to wait until the drug-eluting process came off patent. This happened about a year and a half ago. This is advantageous to us as all our patents have been issued in the last year and a half, so we have quite a long period of time of patent protection. Recently, we reached an agreement with New Brunswick, Canada to begin clinical trials there, which we expect to begin in about two months. On October 13th and 14th, we will be a major sponsor of the European bifurcation club. This is an invitation only event for the top 200 interventional cardiologists in Europe and Dr. Khorsandi will make a presentation at this event highlighting the ABS technology. Right after that, there is the TCT conference, a cardiology conference in Denver and we will be there as well. While all of this is happening, we will be preparing our regulatory submissions for both our CE mark and for the FDA. We expect to have our submissions ready in the second half of 2018. We have done patients previously outside of the U.S. and there is a predicate device which has received approval, so we are hopeful that we can follow the same process.

“There are many reasons to look at Advanced Bifurcation. We are not re-inventing the stent. We are taking a tried and true product and improving both the process and the outcome. As a result, more interventional cardiologists will be able to do the procedure with less risk and in a shorter amount of time. Bifurcation stenting, which was once the domain of only the most skilled professionals at prominent medical centers, will become safer for the patient and widely available to others who may need the procedure. This product benefits everyone involved – patient, physician, hospital and payor.”- Charles Laverty

CEOCFO: What has been the reaction from members of the medical community who have seen your approach?

Mr. Laverty: At first, they are a little bit skeptical that we have perfected the process. But when they see it, the first question they have is when they can get the product and start using it. Actually, the reaction has been quite overwhelming. We expect that this product will expand the market. For example, in Southern California there are probably only four hospitals that might do bifurcations, Cedar Sinai, Scripps, UCLA and possibly Loma Linda University Medical Center. All the other hospitals, about 800 of them, will have the ability to do bifurcations when our product is available. The process is simple and requires limited training. Now, they must refer a patient out to another hospital if there is a problem or the person will go for open heart surgery. This product is good for the patient, the physician, the hospital, and the payor.

CEOCFO: What do you understand from your background on bringing a product like this to market?

Mr. Laverty: I have been doing this for thirty years and the reason I am excited about Advanced Bifurcation is that this is a “need to have product”, not a nice to have. This really solves an issue in the interventional cardiology space. I think ABS will ultimately be very successful because we have something that people need, that nobody else has and we have developed very strong IP to protect it. To give you an example, it is very difficult to get patents in China and Japan, and we have been able to get them in both countries. So, that gives you some indication of what we have here.

CEOCFO: How do you test the long-term effect? How are you able to be sure that over time, it will continue to be affective and not harmful?

Mr. Laverty: First of all, stents have been used and in the market for at least ten or fifteen years if not more with an excellent safety profile. Our process is just a modification on existing technology. For our procedure, we expect to follow them every thirty days and will do a one year follow-up as well. After a year, if the patient has no restenosis, which is the buildup of plaque, then there is nothing else that can happen to the patient in this case.

CEOCFO: Are you funded for your next steps? Are you seeking partnerships?

Mr. Laverty: Most of our money has come from the management and from family and friends. We have secured a bank credit facility. We retained an investment banking firm by the name of Healthios, which is out of the Chicago area and focuses primarily on healthcare. We are very pleased with them and are in the process of raising twenty million dollars right now. We have been working with them for about three months and are in due diligence with a number of interested parties right now.

CEOCFO: *With so many companies in health to pay attention to, why look at Advanced Bifurcation systems?*

Mr. Lavery: There are many reasons to look at Advanced Bifurcation. We are not re-inventing the stent. We are taking a tried and true product and improving both the process and the outcome. As a result, more interventional cardiologists will be able to do the procedure with less risk and in a shorter amount of time. Bifurcation stenting, which was once the domain of only the most skilled professionals at prominent medical centers, will become safer for the patient and widely available to others who may need the procedure. This product benefits everyone involved – patient, physician, hospital and payor.

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