

# THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

## Cardica, Inc. (CRDC)

**BERNARD A. HAUSEN** has been President and Chief Executive Officer of Cardica, Inc., since December 2000. Dr. Hausen cofounded the company in October 1997 and has served as a Director and Chief Medical Officer since inception. He received a medical degree from Hannover Medical School in Germany in 1988 and was trained there as a General and Cardiothoracic Surgeon. Upon completion of his training, he received a Ph.D. in medical physiology in 1999. From 1996 to 2000, he was employed as a Senior Research Scientist in the laboratory for transplantation immunology of the Department of Cardiothoracic Surgery at Stanford University. Until Dr. Hausen became a full-time employee of Cardica in October 2000, he remained responsible for all surgery-related research in that laboratory.

### SECTOR — HEALTH SERVICES

**TWST:** Would you give us a brief history of Cardica as well as an overview of what the company does?

**Dr. Hausen:** Yes. Cardica was founded in 1997 as a medical device company with our primary focus on creating stapling technology that could be used to connect blood vessels particularly in cardiac surgery. At that point, all blood vessel connections in cardiac bypass surgery were performed using suture and hand-sewn techniques. That dates back to the start of coronary bypass surgery about 40 or 50 years ago. The idea we had was that in general surgery, plastic surgery and thoracic surgery, stapling technology had become the gold standard to connect or divide tissue. And so the question was: Could we develop a stapling technology that was miniaturized, so it could deal with blood vessels down to a millimeter?

It took us about three to four years to develop our first stapler. We went into clinical trials and showed that our stapling technology was not only small enough to do so, but could very reliably and very repeatedly connect very delicate blood vessels, such as coronary arteries. We obtained FDA clearance for various products between 2006 and 2008, and went public in 2006 to get additional funds to be able to commercialize these very promising products.

We built up a sales force, and at the time we needed more money to expand our sales force and to turn us into a profitable enterprise, the stock market crashed, which was the end of 2008 and beginning of 2009, as you very well recall. We had no choice but to downsize our cardiac organization and focused on raising additional funds to develop our proprietary miniaturized stapling technology for general surgery and thoracic

surgery. In these markets, stapling had already become the gold standard, and we wanted to develop smaller and more flexible products that would allow surgeons to do more minimally invasive surgery. We maintained our presence in cardiac surgery with a much smaller sales force.

It took us roughly two and a half years to develop the first stapler, and our second MicroCutter product received CE marking in March of this year. We are in the middle of doing clinical evaluations, and a European clinical trial is underway. We expect to begin selling in Europe in the very near future.

**TWST:** Please explain the concept behind laparoscopic technology.

**Dr. Hausen:** The surgery for anything in the abdominal or thoracic cavity traditionally was done through large incisions. Surgeons would take a knife and open up the abdomen or open up the chest wall and use chest retractors or abdominal spreaders and create an opening where they could get their hands in, where they could get their needle holders and forceps in. Basically, they did whatever surgery was necessary, manually.

And about 25 years ago, this changed with the introduction of stapling technology. Stapling technology allowed surgeons to avoid an incision, and instead just put in little trocars, which are little ports between five and 15 millimeters in diameter through which they would insert instruments and use a camera to look in an inflated abdomen or chest wall or chest cavity.

Using trocars, surgeons are now able to perform the same procedures — lung resections, bowel resections, bowel diversions — whatever general or thoracic surgeons do, they can do through a minimally invasive approach. All this came to fruition with the introduction of stapling technology. Today, the largest ports used

during these procedures are for a stapler. The stapling products on the market today, marketed by two major companies, require the largest ports we put into the abdominal or the chest cavity — from 12 to 14 millimeters in diameter. All other instruments — camera, graspers, suturing devices — fit through smaller ports.

Surgeons obviously say they'd rather avoid having to put that big port in, and they'd love a smaller stapler that will fit through a smaller port. The products we develop address the need to be less invasive, and thereby reduce the pain, discomfort, invasiveness and hospital stay, accelerating the time to recovery of the patients that undergo these procedures.

**TWST: Last month, Cardica announced that its MicroCutter XCHANGE 30 had been successfully used over a two-month period in more than 35 procedures in Germany. When will this product resume clinical study in the Europe?**

**Dr. Hausen:** We announced that we resumed the trial on July 24, 2012 in Europe and expect to begin European commercial sales in the second half of 2012.

**TWST: Given your success thus far in Germany, how do you see your R&D expenditures will change in the future in terms of amount and emphasis?**

**Dr. Hausen:** The product is working very well. As we pointed out in our press release, there have been no adverse events that have resulted in a prolongation of hospital stay and no adverse outcomes for the patient, which is what we are looking for as a provider of a new product.

In terms of R&D expense, we anticipate it may increase as we will require further iterations of this product for different applications. Right now, we have our 5-millimeter product. We're planning to do an 8-millimeter product with longer jaws, which we call end effectors, so a surgeon can staple more material, more tissue in one deployment. We foresee a portfolio of about six to

share. Given the size of the market, even a small market share would be quite meaningful for our company in terms of overall revenue.

**TWST: Is the company going to stay in the cardiovascular business as you've described? Do you have any plans to develop a pipeline outside of stapling and anastomotic devices?**

**Dr. Hausen:** Right now, the MicroCutter cutting/stapling devices are our primary focus. The cardiovascular products, which are the first products we developed, we continue to sell through a different distribution arm. In general surgery and thoracic, staplers that we've started to develop three years ago, we will be first selling in Europe and other places outside the U.S. And only when we get FDA approval, will be able to sell it in the U.S.

It is very hard to predict in these times how long that will take to get approval, but I want to emphasize that the markets outside the U.S. are significant. Cardica has enough opportunity outside the U.S. to prove its point and even to become profitable. We don't need to be in the U.S. to do that. It would have been very different if we would have stayed just with our cardiovascular products.

**TWST: Is there any other company developing procedures similar to Cardica?**

**Dr. Hausen:** In the cardiac space, there is no one developing anastomotic devices. In the general surgery and thoracic space, of course, these two main competitors are formidable opponents in terms of product development, but only in terms of iterations they've established. I believe that if they would just follow the same technology path they've taken over the last 25 years, it be very difficult for them to miniaturize their technology without violating our patents. So, yes, they will iterate what they have.

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eight products over the medium term that will provide our sales force with a nice bag of products to be very competitive with the existing stapling product providers in the market today.

**TWST: Please give us your thoughts on what kind of market is available, what kind of market share Cardica technology can address, and what the pricing and revenue opportunities are that you see within that overall market.**

**Dr. Hausen:** That's a good question. It's a huge market. Stapling is one of the biggest medical device markets. In the U.S., there is about \$800 million in laparoscopic stapling products sold annually; and worldwide, probably more than double. If you add sealing applications, some of which could be stapled, especially with our smaller staplers, you are probably doubling that number one more time. We believe the total market is between \$2 billion and \$5 billion in sales.

While we are a very small company and we're competing with very, very big companies, it's difficult to forecast our market

Will they be able to jump in the space that we're trying to address? I think that would take them some time, and I think that's where we have a real opportunity where we don't see any competition. We're going to be in the smaller stapler space and have it to ourselves for some time.

**TWST: Have you been doing this alone thus far? Do you have partners?**

**Dr. Hausen:** We have had joint product development relationships with Cook Medical and with Guidant that was acquired by Boston Scientific.

But in terms of the MicroCutter product line, which is the general surgery and thoracic stapling product, we are on our own. There is nobody we've partnered with.

**TWST: How strong is the intellectual property portfolio with Cardica?**

**Dr. Hausen:** I think it's extremely strong. We've filed very early patents on our microstapling technology for cardiac

surgery and have issued patents on the technology that's required to miniaturize the general surgery and thoracic stapling products, i.e., the MicroCutter product line. Because of our unique approach, I think our I.P. position is very strong.

**TWST: When you look at Cardica's technology and some of the other technology or processes out there, what roles may mergers and acquisitions play to grow the company's portfolio or perhaps add to the portfolio at large?**

**Dr. Hausen:** General and thoracic surgical procedures require an array of products, not just stapling products. There are a number of companies outside of the two that make stapling products that offer some of these other products. Applied Medical, Bard, Aesculap, Stryker, just to name a few, are companies that sell other parts, other products needed in these procedures. So it is conceivable that we could join forces with some of these companies. It's also conceivable that we could join forces with one of the stapling companies.

But our focus right now is to show that these are products that — in our hands, independent of anyone else — can become profitable on their own. Then, we can decide if we would like to form an alliance with someone else to further grow the market.

**TWST: Are you a Co-Founder?**

**Dr. Hausen:** I am a Co-Founder, yes.

**TWST: What caused you to cofound this company? What were the challenges and opportunities you saw? And as a personal report card, have you met the goals you've set for yourself?**

**Dr. Hausen:** First of all, I kind of stumbled into this. I'm a Cardiac Surgeon. I was watching a procedure in an animal lab where surgeons tried to hand sew coronary vessels through ports on an stopped heart using some special technology, and I just thought that this wasn't the way to go. It seemed very, very difficult. And time proved me right — it was not possible to do this using hand-sewing technique. I talked to another friend of mine who was an Engineer, and said we should start a company that can develop stapling technology that will create an anastomosis on a miniaturized basis. He jumped on it, and we formed this company, and that's how it all started. Eventually, I left my job as a Cardiac Surgeon and became the CEO of this company.

In terms of my goals, I was hoping we could reach profitability sooner, though there are a number of obstacles to overcome. I think one of the foremost for almost all medical device companies is the FDA. I think that while the intentions may be good, the methods or the whole process within the FDA is not as clearly defined when compared to our experience in Europe. The delay in the FDA clearance processes as a whole caused significant delays in our commercial plans.

The other is the expectation that cardiac surgeons would adopt our cardiovascular products more quickly and more aggressively. I overestimated how open this individual subgroup of surgeons would be for our technology. The correction on our part was, well, if we can't get this group of surgeons to adopt our technology quickly enough to become profitable, then let's take the technology to surgeons who've already shown that they will adopt stapling technology and give them something they've been asking for so many years.

**TWST: What are some of the long-term goals you've set for Cardica, and what are the adjustments or changes or perhaps new developments you believe the company will have to undergo to keep on track to meet these targets?**

**Dr. Hausen:** In the long term, the goal is to become profitable. I think we need to hold the course, finance the company adequately, and continue to develop and refine the technology we're developing right now. I think this is technology that the market is demanding. We've heard it over and over from surgeons, their need for high-quality, very reliable products.

This is not something that happens overnight. You have to get through a learning curve before you have products that are at an appropriate reliability level. We need the time to get through that learning curve. We're in the middle of it. I think we've made great progress. I'm not concerned that we won't pass that learning curve, but we're not at the end of the learning curve. And once we are, we can then broaden our product portfolio and gain more and more market share at least to a point where we become profitable. That is our goal.

**TWST: Looking at the company's current management team and internal operations, are there any planned changes or adjustments in these areas?**

**Dr. Hausen:** I'm very fortunate to have very capable and experienced senior managers on our team. Our CFO has been a CFO of a number of public companies, very experienced. We have a VP of Sales and Marketing who comes from one of the two major stapling companies, so he knows this market inside and out. We have a VP of Operations who has worked for Baxter and Medtronic as a VP of Operations in very similar spaces.

And finally, our VP of R&D developed stapling technologies for one of the major players in the stapling market early in his career, so he knows the technical aspects of surgical stapling over a long career. I could not have a better team.

**TWST: For a long-term investor looking at financial statements and annual reports for Cardica, what would you suggest are the one or two items the investor should focus on over time to gain insight into what the company is doing and where it is going?**

**Dr. Hausen:** This is all about product performance and initial sales overseas. Our execution in this market will tell an investor how promising this investment can be. If Cardica can do what it says it's going to do — resume the clinical trial, show good initial sales with the product in Europe, complete the trial, submit the trial results to the FDA, and eventually get FDA clearance — I think we are on a good track to be a very successful company. So if I were an investor, those are the things I would follow very closely.

**TWST: Summarizing your strategic priorities for the remainder 2012 and into 2013, what's top of the list?**

**Dr. Hausen:** First, resume the trial and start sales of the MicroCutter XCHANGE 30 in Europe. We want to grow a good base of key opinion leaders and customers outside of the U.S. Then for our fiscal year ended June 30, 2013, we expect to have all of the data we need to submit to the FDA, and get FDA clearance for the U.S. market in due time thereafter.

**TWST: Please give us a summary statement for the potential investor. Why should he or she buy the stock today?**

**Dr. Hausen:** Well, very rarely do you find medical device markets that are as big as the one that Cardica is trying to address. Admittedly, there are two major players in the market, but the market is so big that there is plenty of room for more players.

There is a technological challenge in creating these products. Cardica has proven in the past that it can overcome these hurdles with very reliable cardiovascular products, such as the PAS-Port and the C-Port. So I believe that there is a real opportunity for our company with the knowledge it has in successfully developing miniaturized stapling technology in this very large market.

**TWST: Anything you'd like to add?**

**Dr. Hausen:** We are very excited about the future for Cardica and believe that we will be able to effectively meet

clinical needs for miniaturized and flexible staplers for our surgeon customers and their patients, provide rewarding opportunities for our employees and create value for our shareholders.

**TWST: Thank you. (KL)**

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