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# THE WALL STREET TRANSCRIPT

**Questioning Market Leaders For Long Term Investors**

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**THE WALL STREET TRANSCRIPT**

## COMPANY INTERVIEW

**PAUL MCCORMICK**  
Endologix, Inc.

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# Endologix, Inc. (ELGX)



**PAUL MCCORMICK**, President and Chief Executive Officer of Endologix, Inc., has more than 27 years in the medical device industry. Mr. McCormick joined Endologix in January 1998 as Vice President of Sales and Marketing, and served as President and Chief Operating Officer from January 2001 until January 2003, when he became President and Chief Executive Officer. Previously, he held various sales and marketing positions at Progressive Angioplasty Systems, Heart Technology, Trimedyne Inc., and US Surgical Corporation.

## SECTOR – MEDICAL DEVICES

### (AFK610) TWST: Tell us about Endologix.

**Mr. McCormick:** Endologix is the developer of the Powerlink® System, which is a minimally invasive technology to treat abdominal aortic aneurysms, commonly referred to as AAA. This is a weakening of the wall of the aorta — the largest artery in the body — which results in a balloon-like enlargement. Once the AAA develops, it can continue to enlarge, becoming susceptible to rupture, which is life threatening.

The clinical literature indicates that if an AAA ruptures, approximately 50% of those persons will die before reaching the hospital. Of those who do survive to reach the hospital, half will succumb to complications of the rupture or from surgery.

The patient who is fortunate enough to have an AAA diagnosed prior to rupture is usually sent for a CT scan to characterize the shape and the size of the aneurysm. Conventional treatment is open surgery, in which a surgeon through a midline incision moves the intestines aside to gain access to the aorta. The surgeon then clamps above and below the weakened segment, opens up the aortic

sac, sews in a surgical graft and then puts everything back together again.

This procedure carries a surgical mortality rate of 3% to 8%. To put this statistic in perspective, the rate of mortality with open-heart bypass surgery is slightly less than 1%. The conventional AAA procedure also carries a serious morbidity rate in the 15% to 40% range, including complications such as stroke, and requires a long recovery period. This conventional procedure is a very tough operation on patients who are typically more than 68 years of age.

The Powerlink is our stent graft to treat AAA in a minimally invasive manner. A stent graft is a metal cage or scaffold covered with material. These devices are compressed and loaded into small catheters. These catheters are inserted into the body through the artery of the leg into the abdominal aorta, where the stent graft is then deployed. Once in place, the stent graft acts to shunt blood flow away from the weakened aortic wall, which reduces the pressure and the risk of rupture. Many patients are able to be treated under a regional or local anesthetic.

Endologix gained FDA approval for the Powerlink System in late 2004 based on excellent

clinical results from our pivotal trial and we initiated a focused US launch in early 2005. This year we began a much broader domestic commercialization of our Powerlink, so this is an incredible time for Endologix.

**TWST: Tell us about your 2006 accomplishments and what to look for in the next 12 months.**

**Mr. McCormick:** We have had a very productive year at Endologix. Powerlink sales are materializing due to steps we are taking to accelerate domestic uptake. Our success is indicated by our sequential domestic quarterly sales growth of 21% in the third quarter, our most recently reported quarter, versus second quarter sales. We began 2006 with 23 sales territories, and we are on track to hit our goal of increasing our sales force headcount to 45 to 50 by year end.

We also strengthened our balance sheet through a \$20 million direct equity placement completed in June. We now believe that our funds are sufficient to support our operating and R&D activities and take us to positive cash flow from operations.

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***“We are participating in a large and growing market, with more than 1.7 million Americans with some stage of AAA disease. There is a growing movement toward alternatives to conventional surgery and the Powerlink offers a minimally invasive solution. The Endologix Powerlink has a competitive advantage of demonstrated long-term durability.”***

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Additionally, we continue patient enrollment in two clinical trials aimed at supporting Powerlink use in patients with large aortic necks. We believe that about 10% to 15% of AAA patients fall into this category.

Going forward, we see an incredible opportunity for Endologix. Currently the market for minimally invasive AAA treatment is greater than \$300 million in the US alone. This market is expected to grow to the \$500 million to \$600 million range by 2009.

It’s driven by a couple of factors. As the population ages, the number of patients with AAA is growing. Additionally, in January 2007, Medicare will begin screening for AAA disease.

Additionally, we expect to obtain approval in the Japanese market and to launch the Powerlink System commercially sometime in the second half of 2007. We will be one of only two manufacturers to obtain a Shonin approval.

Further, we are leveraging our core competencies in this technology to other applications such as thoracic dissections to build out Endologix as a stand-alone company.

Again, we see 2007 as a time for accelerated growth at Endologix.

**TWST: Tell us about the Powerlink in terms of the competitive landscape.**

**Mr. McCormick:** The Powerlink has distinct design advantages over the other three AAA devices approved in the US. The Powerlink is a unibody system that appears like an upside down “Y” where the two legs of the “Y” are in the arteries of the legs and the long straight section is in the aorta.

The other three FDA-approved stent grafts are multi-piece, or what is referred to as modular stent grafts. This means the physician must actually assemble the various pieces inside the patient to form this Y-shape, utilizing various wires and catheters. Over time the multi-pieces can separate or migrate, leading to blood flow back into the aneurysm sac, which puts the patient again at risk. A one-piece system, like the

Powerlink, obviously cannot come unattached. Additionally, the Powerlink sits near or at the bifurcation of the aorta, which inhibits downward movement of the device.

The Powerlink has an outstanding record for device durability. There are no reported wire fractures throughout our follow-up period with many patients now tracked for more than six years.

We believe that the dependability of the Powerlink clinical results and the durability of its design will ultimately drive product adoption and take competitive business.

**TWST: Introduce us to your top-level management team.**

**Mr. McCormick:** Endologix's outstanding management team has more than 140 combined years of industry experience. All have been involved with companies that have executed on similar business plans.

Frank Brown, our Chairman and past Endologix President, has been with the company for almost 10 years. He came to Endologix as an investor when the company was private. Frank sits on a number of medical devices boards and has a history of building out medical device companies.

I have been with Endologix for almost nine years. My entire career has been with medical device companies that were focused on changing patterns, including Progressive Angioplasty Systems, Heart Technology, Trimedyn and U.S. Surgical.

Karen Uyesugi, our Vice President of Regulatory Quality and Clinical Affairs, has experience with both large and small medical device companies and has been with Endologix for nearly eight years.

Roughly three years ago Dr. Stefan Schreck joined us. Dr. Schreck, who formerly was with Edwards Lifesciences and an Assistant Professor at USC, came to Endologix to help build

out our current technology and look for opportunities to leverage our core competencies.

Bob Krist joined Endologix as CFO at about the same time as Dr. Schreck. He has brought us public company experience that has been invaluable. He is also charged with helping to build out our infrastructure.

**TWST: What has been your financing history to date?**

**Mr. McCormick:** We have done an outstanding job since becoming a public company. Following 9/11, the capital markets were challenging. We were looking to do a financing and decided upon a reverse merger into a public entity, which was completed in May 2002.

This meant at the time we effectively went public, we had no analyst coverage and had to start from scratch at educating the investment community about the opportunity Endologix presented. We laid out an aggressive set of company milestones and then executed on these milestones.

Since the time of our reverse merger, we have completed four successful financings, raising more than \$58 million. Along with our financings, we have attracted outstanding institutional ownership, including groups such as Federated Investors, Elliott Associates, Goldman Sachs, Missouri Valley Partners, Forstmann-Leff, and Perkins Management.

With our last financing completed this past summer, we have publicly announced that we believe our cash is sufficient to take us to cash flow positive from operations. We are in outstanding shape from a balance sheet standpoint.

**TWST: What is being done within the medical community to increase awareness of AAA and the Powerlink?**

**Mr. McCormick:** Detection is what makes this disease so terrible. The vast majority

of patients exhibit no symptoms. Oftentimes the first symptom is a rupture that is accompanied with about a 75% mortality rate. The actual number of deaths due to AAA may be higher than reported because without autopsies, many cases may be charged off to sudden cardiac death or some other condition.

Most AAA diagnoses, and there are about 200,000 made every year, come incidentally. For example, a urologist happens to be doing an ultrasound screen of the bladder and discovers an aortic aneurysm.

That's the important aspect of the SAAAVE bill that was passed by Congress earlier this year and becomes effective January 1, 2007. Physicians will begin using ultrasound screening for AAA in certain individuals entering the Medicare system. We believe the SAAAVE bill will have a significant impact on the number of patients looking for treatment in the coming years.

We are working to increase recognition of AAA and the Powerlink within the medical community. Our outstanding clinical results are being presented at medical conferences and meetings, including five- and six-year follow-on data with an extremely high compliance rate. We can account for 97% of all patients who were treated in our pivotal trial. Our data is also being published in peer-reviewed medical journals. This type of physician outreach builds support from clinicians as they determine which technology to employ for their patients.

I would like to add that we have a tremendous resource in our Website, where we have published clinical data available for those evaluating the impact of the Powerlink. I would encourage those who are interested to visit [www.endologix.com](http://www.endologix.com) to be able to review the strong clinical results from this technology.

**TWST: What do the overseas markets look like?**

**Mr. McCormick:** The European market is estimated to be anywhere from \$70 to \$100 million in sales and growing at 10% to 20% each year as that population ages and as they become aware of the disease through screening.

Japan, interestingly enough, has no commercial devices at this point. Endologix was the very first company to complete a clinical trial in Japan. We've submitted our documentation and are in contact with the regulatory authorities in Japan. Our expectations are that we will receive our approval soon and, following the establishment of reimbursement, we'll introduce our product. We expect to launch in the second half of 2007, making us one of only two devices approved and launched in Japan. So that's a significant upside as we move forward.

We now have distributors in place in the major European markets as well as in Japan. However, our focus will be on the domestic market because of the lower average selling prices overseas and the fact that procedures with the Powerlink require clinical support.

**TWST: In terms of investment community outreach, what do you find important at Endologix?**

**Mr. McCormick:** We've been fairly aggressive about introducing Endologix to the investment community; however, we still remain below the radar screen, which is why I believe we trade at a fairly modest valuation at this stage.

**TWST: Where is Endologix in terms of resources for manufacturing, delivery, and available inventories?**

**Mr. McCormick:** We now have the appropriate infrastructure to take us forward over the next couple of years. We have given guidance that

our expenditures, other than sales and marketing, will remain relatively flat. We believe growth is just a function of expanding our sales and marketing efforts, executing basic blocking and tackling, and leveraging all of our other resources as we build up the business.

**TWST: What compels investors today to include Endologix as part of their current portfolios and in their longer-term investment strategies?**

**Mr. McCormick:** When you consider what investors look for in a medical device company, Endologix has it. We are participating in a large and growing market, with more than 1.7 million Americans with some stage of AAA disease. There is a growing movement toward alternatives to conventional surgery and the Powerlink offers a minimally invasive solution. The Endologix Powerlink has a competitive advantage of demonstrated long-term durability. We see those as three important keys in capturing the attention of the investment community.

The Powerlink is already demonstrating product acceptance and uptake with significant

sequential quarterly sales growth and as we move forward we expect to see continually increasing product sales. Additionally, we expect to be one of the two first commercial products in Japan, with the Powerlink launch in the second half of 2007. We have a robust pipeline of products to fuel future growth and we have a strong balance sheet that can support our R&D activities and take us through to positive cash flow from operations.

I would say that Endologix presents a very attractive opportunity for those who invest in medical device companies.

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

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