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Edwards: Battling the Innovator's Dilemma

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By Stephen Levin

High on the holiday wish list for any senior executive of a major device company, right up there with being thinner and looking younger, is the desire for market leadership. But those executives rarely admit that having a successful product franchise can be as much a curse as a blessing, particularly in medical devices where product development cycles tend to be relatively short. New product iterations seem to happen overnight and game-changing next-generation technologies are produced with remarkable frequency. The challenge then for most successful large device companies is to maintain their product leadership positions by continuing to iterate current products and drive sales and marketing efforts, while simultaneously dedicating the R&D or M&A resources necessary to develop the next-generation product that may obsolete their current franchise device.

That innovator's dilemma is the situation currently confronting Irvine, CA-based Edwards Lifesciences Corp. Indeed, the company could serve as a case study for Harvard Business School professor Clayton Christensen who made that phrase part of the business lexicon when he published "The Innovator's Dilemma" in 1997. When Edwards emerged in April 2000 as the publicly traded spin-off of Baxter International Inc. 's cardiovascular group, 80% of the new company's revenues were generated by products with worldwide market leadership positions. *[See Deal]* And the company has maintained those franchises, particularly in heart valves and critical care products. (*See "Edwards: Will a Biotech Deal Strategy Work for a Device Company?"* IN VIVO*, September 2002 (Also see "Edwards: Will a Biotech Deal Strategy Work For a Device Company?" - In Vivo, 1 Sep, 2002.).)*

Edwards has built its market-leading franchises primarily by selling to the same customer group: cardiac surgeons. This has left the company vulnerable to one of the most important challenges in cardiovascular devices: the continuing encroachment by interventional techniques and technologies on cardiac surgery. With the development of stents, bare metal and drug-eluting, and the slower-than-anticipated adoption of minimally-invasive cardiac surgery techniques, interventional cardiologists have been increasingly performing procedures that were formerly the province of surgeons, both in core segments such as coronary artery disease where angioplasty and stents have largely supplanted bypass surgery, and in emerging therapeutic areas like carotid disease, where stenting is quickly gaining ground against carotid endarterectomy (CEA) surgery.

Indeed, even in heart valves, Edwards' flagship franchise, the hottest potential area of technology development over the next several years will be minimally-invasive and percutaneous techniques for heart valve replacement and repair, a trend, again, likely to benefit interventionalists at the expense of surgeons. Edwards saw the writing on the wall and recognized that it would have to address this dilemma on two fronts. First, in order to protect its core heart valve franchise, the company would have to invest heavily in these new approaches--many of which are at least several years from commercialization--while maintaining its leadership in the traditional surgical valve market. *(See "In Heart Valves, a Brave, New, Non-Surgical World,"* START-UP*, February 2004, (Also see "In Heart Valves, a Brave, New, Non-Surgical World " - Medtech Insight, 1 Feb, 2004.) and "Edwards' Winning Heart Valve Strategy,"* IN VIVO*, April 2002 (Also see "Edwards' Winning Heart Valve Strategy" - In Vivo, 1 Apr, 2002.).)*

Edwards also recognized that cardiovascular medicine was shifting towards interventional procedures because of the benefits that percutaneous approaches produced for patients, physicians, and payers. The company saw the need to get ahead of this growth opportunity by developing products for a new customer group—interventionalists--in order to remain a viable player in the cardiovascular market while continuing to serve their core customers--surgeons.

The biggest challenge for Edwards in this market expansion effort was identifying an interventional product segment in which the company could develop market-leading products, having only limited catheter-based expertise. It also needed to find a space large enough to provide the growth opportunity the company needed. The area that Edwards chose to focus on was peripheral vascular (or artery) disease (PVD/PAD).

Broadening Your Base

Treating peripheral disease is not completely new territory for Edwards. Indeed, one of the company's best known products, its *Fogarty* embolectomy catheter, was the first catheter-based technology used to remove blood clots from limbs. But the *Fogarty* catheters were surgical products. What Edwards was now looking to do was develop a line of interventional devices to

treat PVD. "We felt that our *Fogarty* product line gave us an advantage in terms of understanding peripheral disease, and that our relationships with surgeons gave us a base of business in this area and a starting point to expand into interventional applications," recalls Michael A. Mussallem, Edwards' chairman and CEO.

Indeed, notes Stuart Foster, corporate VP, technology and discovery, Edwards identified PVD as a target opportunity as long ago as 2001, a year after the spin-off from Baxter. There were several reasons why the peripheral market attracted Edwards' attention. First, there is a large unmet clinical need because PVD is under-diagnosed and under-treated, largely because few effective therapeutic options currently exist. As a result, Edwards believed the peripheral stent market could grow in excess of 15% annually, largely in the US, simply by treating patients who now weren't treated. (Peripheral stenting includes biliary, renal, and iliac stents, along with SFA/popliteal, which is the largest segment of the market. *See Exhibit 1.)*

"All of the demographics are favorable because as more and better less-invasive treatments become available for peripheral vascular disease, the condition will be treated more often. The diagnosis is relatively simple to make, and often occurs in patients who already have coronary artery disease," Foster explains.

Edwards also thought that establishing a base in peripheral disease would enable the company to develop interventional capabilities for future therapies, including percutaneous heart valves. "We recognized that there were common technology capabilities in developing interventional products, whether to treat peripheral arteries or heart valves," Foster suggests. Key among these was the ability to design and manufacture stents and stent delivery systems.

The competitive landscape in peripheral artery disease also appeared less daunting to Edwards than in other interventional cardiology markets. "When we looked at the peripheral vascular market, from our perspective, the major coronary device companies, who were also the dominant players in the peripheral market, were very focused on drug-eluting stents for coronary applications, and less focused on the peripheral market," Foster says.

Good for the Heart, Not the Legs

The early efforts to treat PVD percutaneously were characterized by attempts by large coronary device companies to migrate stent technology that had proven successful in treating coronary or biliary artery disease down to the legs, where they were used off-label in the US. Most of those efforts have failed, largely because the companies underestimated the challenging anatomical nature of peripheral vessels, particularly the superficial femoral artery (SFA). Indeed, the repeated failure of coronary-based stents in peripheral vessels was largely responsible for peripheral stenting not being widely adopted since many physicians came to believe that stenting would succeed in the periphery. That view still largely exists today and represents a

significant obstacle for Edwards and its competitors to overcome.

"Physicians generally say that the SFA is the most diseased vessel in the body," Stu Foster explains. Coronary disease typically involves small, focal lesions, while peripheral disease is generally characterized by long, diffuse lesions. Whereas most coronary lesions are in the one-to--two centimeter range in vessels roughly two-to-three millimeters in diameter, in the SFA it is not uncommon for patients to have lesions as long as 20 centimeters in an artery that can be seven millimeters in diameter. "The gross amount of pathology in peripheral disease is exponentially greater, so to think that you could easily migrate coronary technology, whether bare metal stent or drug-eluting, into a vessel like the SFA was overly optimistic," he says.

In addition to the differences in vessel size and the nature of the disease, the peripheral vessels present a different set of mechanical force challenges that coronary arteries never encounter. Just think about how many times a day you bend your leg and imagine the flexion forces that are applied to those peripheral vessels. That is what a peripheral stent would have to survive; coronary vessels, by contrast, are not subject to those kind of mechanical forces. Thus, a peripheral stent has more in common with a carotid stent than with a coronary device in terms of requiring greater radial strength to avoid being crushed and fractured.

In Edwards' view, not having an existing interventional coronary business proved to be an advantage. "We used to say that we were unencumbered by coronary leverage," Stu Foster recalls. "What we meant is that we didn't believe that the right solution to peripheral vascular treatment was to take coronary products and try to make them work in peripheral applications. Peripheral stents need to be purpose-developed for use in the peripheral vasculature and, in the case of stents, they may or may not have anything in common with a coronary stent. When you look at a coronary and a peripheral stent, they don't look like the same product, and they aren't," he explains.

For that reason, Mike Mussallem notes, the presence of other large cardiology companies in the peripheral market did not deter Edwards. "There are a number of good companies already involved with peripheral stenting, but we didn't believe that they had applied their best efforts because they also had incredible opportunities on the coronary side, particularly with drug-eluting stents, and they appropriately applied their resources to those coronary products," he suggests.

But if Edwards had certain advantages in its understanding of the peripheral market, the company also had one significant disadvantage: it had virtually no internal expertise in what Mike Mussallem calls "the single biggest device opportunity in the treatment of peripheral vascular disease," i.e., stents. Whether bare metal or drug-eluting, coronary or peripheral, stents are the defining products of interventional cardiology. Yet other than the work done developing its *Lifespan* AAA (abdominal aortic aneurysm) stent graft (which the company has since sold to

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Angiotech Inc.), Edwards has little experience in designing or manufacturing stents or the equally important component of stent delivery systems. *[See Deal]*

Finding the Right Stent

The fact that previous stents had failed in the periphery and that the company had very limited internal stent competency, did not deter Edwards. "We believed that stents had been under-utilized in peripheral vascular disease not because they wouldn't work but because the right stents had not yet been developed for that application, particularly for the SFA," Stu Foster says. Edwards' strategy was to become the leader in the SFA segment by developing a stent specifically designed for that indication, taking advantage of this potentially large market opportunity. *(See Exhibit 2.)*

Moreover, Edwards' strategy would rest not just on building up internal expertise in stenting, but on tapping into its long-standing relationships with surgeons, who primarily treat patients with PVD (along with interventional radiologists and cardiologists). "We gained a lot of confidence from the feedback we received from key physician opinion leaders with whom we had worked over the years. They were the ones who really convinced us that PVD stenting was an unmet opportunity, and encouraged us to take this on because the other big companies in the field weren't paying enough attention to this clinical issue," Foster recalls.

According to Foster, the stents being used in the periphery were unsuccessful both in terms of clinical results—they led to high restenosis rates—and durability—there were unacceptably high rates of stent fractures. Edwards recognized that it needed to develop or acquire stent technology superior to what is already on the market. Lacking internal stent development capability, the solution had to come from outside the company. "It would have been nice if we could have gone out and done a substantial acquisition to give ourselves a jumpstart on the peripheral stent technology and manufacturing capability, but we just didn't find anyone out there," Mike Mussallem explains.

The solution to Edwards' stent problem ultimately came from two sources that, though across the country from Edwards, were practically next to one another. In South Florida, former Cordis Corp. (now a Johnson & Johnson company) employees launched two small medical device companies: Orbus Medical (now OrbusNeich) and Syntheon Corp. Orbus had developed a balloon-expandable, triple helix design stent that it was selling outside of the US for coronary applications and had a self-expanding version on the drawing board. Syntheon had broad experience in catheter design and was working on a self-expanding version of the same stent, along with a delivery system. In 2001, Edwards acquired the rights to use both the balloon- and self-expanding versions of that stent, along with the delivery system, in the peripheral vasculature. *[See Deal]* (Generally, balloon-expandable stents are used in vessels that are not subject to significant mechanical forces like the SFA, where a self-expanding stent would provide

better durability.)

Stu Foster describes these as "R&D contract deals with some royalty opportunities," that gave Edwards the right to convert them to internal R&D projects, which the company exercised earlier than planned as Edwards built its internal stent design and manufacturing capabilities more quickly than expected. By 2003, the company had moved its stent development in-house. "While we built our internal competencies, the Orbus and Syntheon partnerships gave us a quicker start than we could have accomplished on our own," Foster says.

Having acquired the stent expertise, the next challenge for Edwards was execution, one that company executives acknowledge proved problematic. "It has taken us longer and cost us more to develop these stents than we'd originally thought," Foster admits. "But the good news is that these difficulties have helped us develop greater internal expertise."

The first problem occurred with the delivery system for the self-expanding stent. Helical stents generally have the advantage of greater flexibility, but they also are harder to deliver with precision. Thus a good delivery system is particularly important for precise placement. Edwards encountered both manufacturing and deliverability problems with its initial delivery system and pulled it off the market early in 2004 so the product could be re-designed, a process that Foster says cost the company six-to-nine months time.

And Edwards might not be out of the woods yet. An industry executive familiar with Edwards' *Lifestent* system said the company is still facing problems that are slowing adoption with the re-designed delivery system because deployment continues to be a challenge and predictable placement can be difficult. A next-generation delivery system is due in mid-2006.

Delivery system problems aside, Edwards also ran into manufacturing supply issues through the first half of 2005. It wasn't until the middle of this year that the company was able to fully supply their channel with the full amount of inventory, which is critical in a consignment market such as stents. According to Stu Foster, the company has resolved the manufacturing problems and inventory constraints, and is providing the necessary number of stents and delivery systems as it moves into its Phase II clinical trials.

To Trial or Not?

Over the past ten years or so, interventional cardiology, perhaps more so than any other clinical specialty, has been driven by evidence-based medicine. Randomized clinical trials have been critical in driving physician adoption of coronary stents, both bare metal and drug-eluting, and are being carried forward into emerging areas such as carotid stenting. Peripheral vascular disease, however, has largely been the exception to the evidence-based medicine rule, with few clinical trials in this area.

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More importantly, the few trials that were done weren't particularly encouraging about the efficacy of peripheral stenting. The initial clinical trials comparing peripheral angioplasty with stenting were done using older stents such as the *Wallstent* from Schneider (now part of Boston Scientific Corp.) and the *Palmaz-Schatz* stent from J&J's Cordis. "The early clinical trials data were poor. Stenting didn't look any better than balloon angioplasty, which discouraged wide adoption of stenting in the SFA," explains Stu Foster, who points out that the trialed stents are no longer used in the SFA.

The next peripheral stenting trial was conducted using the *Intracoil* stent (now part of ev3 Inc.), the first nitinol device studied in the periphery. The *Intracoil* stent proved safer than angioplasty, but failed to deliver improved restenosis rates. The *Intracoil* stent was approved by the FDA, but has not been widely adopted, and failed to dispel the widespread skepticism regarding peripheral stenting.

And the next major peripheral stent trial only added fuel to the skeptics' fire. Cordis conducted an arm of the SIROCCO trial comparing its drug-eluting *Cypher* stent with a bare metal stent in the periphery. The trial produced mixed results. It was a failure—the only one to date—for the drug-eluting stent (because of late catch-up at 18 months), but the bare metal stent showed the best efficacy to date in terms of preventing restenosis.

Along with those good results, however, came another dose of bad news for peripheral stenting—the stents fractured at a significant rate. This was the first indication that this new generation of nitinol stents could also have a durability problem in the peripherals. The subsequent FESTO trial confirmed the fracture problem with nitinol stents, showing that the fractures occurred at a widely varying rate depending on the stent. The net effect was to cast a further pall over peripheral stenting, slowing adoption even more.

In the meantime, other technologies were emerging to treat peripheral artery disease, including approaches such as atherectomy and lasers that had either failed or been relegated to niche coronary applications but were being revived for peripheral vessels. The most successful such tool has been the *SilverHawk* atherectomy device from FoxHollow Technologies Inc. , which has seen booming adoption particularly among interventional cardiologists. FoxHollow has chosen to use a registry (TALON), rather than a randomized clinical trial, to develop clinical data on its system. That choice has brought the company criticism from certain interventionalists accustomed to evidence-based medicine's reliance on randomized trials, although it clearly hasn't hampered adoption.

For Edwards, the history of clinical studies in the peripherals presented a choice between conducting a randomized trial, despite the poor history of such studies in peripheral stenting, or relying at least initially on a registry, which would be less expensive and produce data more quickly. According to Stu Foster, there was never much of a choice. "We believed that the only

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way to really prove that the *Lifestent* was a better stent for the SFA was to do a randomized clinical trial that would clearly establish that we had best-in-class restenosis and durability rates," he says.

In addition, Edwards was looking to get specific indications, particularly for the SFA, in its FDA approval, which could best be accomplished using randomized trial data. Indeed, the FDA encouraged the company to do such a study primarily because they were uncomfortable with all the off-label stent usage.

The result was the RESILIENT trial for the *Lifestent* system. "We have three objectives in doing this study," Foster explains. "First is to attain regulatory approval of the *Lifestent* system for the SFA. Next is to show that our stent is much better than balloon angioplasty in order to encourage growth in the market through additional use of stents. And finally, we're looking to demonstrate superior restenosis rates and to dispel concerns about excessive fractures by showing durability."

Edwards unveiled its initial RESILIENT data at several clinical conferences this fall. Six-month data on the Phase I 20-patient cohort showed encouraging results, with a 7% restenosis rate and no fractures. The company expects twelve-month data to be available in the spring of 2006. Edwards continues to enroll patients in its Phase II trial at more than 20 sites, working towards a goal of FDA approval late in 2007. Stu Foster acknowledges that the specter of previous peripheral stent failures remains strong and has hindered patient enrollment.

R&D Boost

If there's a silver lining to the delays that affected Edwards' *Lifestent* peripheral vascular program, it is that they forced the company to expedite development of its internal interventional R&D capabilities. Incorporating less invasive and percutaneous competencies across all of the company's product lines has been part of Edwards' strategy to respond to changing market demands. "Our goal is to become more interventionally capable in each of our primary business areas—peripheral disease, heart valves, and critical care—because we know that patients prefer these kind of procedures," says Mike Mussallem.

Mussallem acknowledges that this has required Edwards to significantly expand or enhance its internal skill sets in a number of different areas, from R&D, most critically, to sales and marketing. "Our move into interventional technologies meant building very different R&D capabilities along side our existing competencies," he points out. "This has produced a tremendous change in our R&D efforts that has been translated to the rest of the company through our operations and our sales force."

Enhancing Edwards' R&D capabilities has been a priority for Mussallem since the spin-off from Baxter. Bringing interventional expertise into a company that has been surgically focused,

without losing its advantage in surgery products, requires a significant boost in R&D. Indeed, where the company was spending roughly 5% of sales on R&D in 2000, Edwards has now doubled that, both in terms of dollars and staff, increasing the research staff to 250. Stu Foster points out that the bulk of the recent personnel additions have been heavily weighted towards those with interventional experience. "We now have an R&D group that is split pretty evenly between surgical and interventional projects," he says.

However, as noted, the additional R&D capacity and expertise were only part of the process of changing Edwards into both a surgical and interventional company. Next was the need to translate that goal throughout the company. "We had to operationalize capabilities within the company that we didn't have before," Foster says. These range from design capabilities such as developing a stent and delivery system, to manufacturing competencies to make those products, to sales and marketing skills that adapt to a much shorter product development cycle than in a market like heart valves.

But for all of the operational and sales and marketing shifts, the most significant adjustment for Edwards lay in the aggressive ramp up of R&D. "We clearly haven't embarked on a channel strategy," says Mike Mussallem. "People don't buy our products because we have the biggest sales force, they buy them because they perform better. We look to develop best-in-class products that can be market leaders. Then, in general, we are able to command premium prices for our products. That's an integral part of our strategy."

Embracing Change

Expanding Edwards' interventional R&D capability has also enabled the company to launch internal programs to develop percutaneous products in its flagship area, heart valves. But much like the peripheral stent program, Edwards decided it could help jumpstart interventional heart valves with an acquisition. In a deal that closed in 2004, the company bought Percutaneous Valve Technologies (PVT) for $125 million plus an additional $30 million earn-out. *[See Deal]* (Edwards also previously acquired Jomed's percutaneous valve program for $20 million. *[See Deal]*) *(See "In Minimally-Invasive Heart Valves, Edwards Cuts a Wide Swath,"* IN VIVO*, January 2004 (Also see "In Minimally-Invasive Heart Valves, Edwards Cuts a Wide Swath " - In Vivo, 1 Jan, 2004.); "Edwards Gets Heart Valve Technology From Jomed,"* IN VIVO*, March 2003 (Also see "Edwards Gets Heart Valve Technology From Jomed" - In Vivo, 1 Mar, 2003.); "Edwards and Cook Combine on Possible Living Heart Valve,"* IN VIVO*, January 2003 (Also see "Edwards and Cook Combine on Possible Living Heart Valve" - In Vivo, 1 Jan, 2003.).)*

Heart valves currently comprise 45% of Edwards' revenue. Although valves, as a whole, are a slower-growth product segment, averaging around 5% annually, tissue valves, in which Edwards is the market leader, are growing at nearly double that rate. Mussallem admits that, at the time of the spin-off, Edwards did not envision the prospect of an interventional heart valve market. As

the market began to emerge, the company was faced with a choice: continue to focus exclusively on surgical valves and maintain market leadership by developing next-generation minimally-invasive surgical (MIS) products, or attempt to continue to drive its surgical valve business while also developing what could be the next-next-generation product, percutaneous valves, for a new physician customer group—interventionalists.

Percutaneous valves were a particularly attractive opportunity, however, because they won't simply replace surgical valves among the current patient population but could significantly expand the valve market. Indeed, percutaneous valves carry the potential of dramatically transforming the heart valve market by providing a treatment option for a large group of patients who currently are not surgical candidates and thus are left without any treatment options. By significantly expanding the potential patient population for heart valves, percutaneous devices may turn this from a slow-growth into a rapidly expanding market, similar to what is currently taking place with ICDs (implantable cardioverter defibrillators).

"We decided early on that, philosophically, we were going to focus on delivering the best heart valve therapy for the patient, and that we were going to be agnostic when it came to the physician customer or the type of procedure," Mike Mussallem explains. "That meant we were not going to walk away from what could be a transformational opportunity in order to protect our base business. If the heart valve business was going to change, we decided that we were going to lead that effort." That leadership was exemplified in an historic valvular heart disease course held in Chicago in September in which, under Edwards' stewardship, cardiac surgeons—through the American Association for Thoracic Surgery (AATS)—and interventional cardiologists—through the Cardiovascular Research Foundation (CRF)—sat down together to discuss the future of heart valve therapy, specifically MIS and percutaneous technologies. *(See "Cardiologists and Surgeons Meet for Heart Valve Summit,"* IN VIVO, *October 2005 (Also see "Cardiologists and Surgeons Meet for Heart Valve Summit" - In Vivo, 1 Oct, 2005.).)*

Recognizing the potential growth opportunity, Edwards launched an internal R&D effort in percutaneous valves. But as interventional valve start-up companies began emerging, Edwards questioned whether an internal program would be the most effective method of developing these new products. "We took a hard look at what it is that makes a small venture-backed company like PVT move faster than an R&D organization inside of a market leader like us," Mussallem explains. Company officials found, not unexpectedly, that Edwards had its market leading position to protect while PVT had nothing to lose, which created a different risk profile. Moreover, where PVT was single-minded in what they were looking to accomplish, Edwards had a number of competing priorities. "That analysis led us to conclude that, organizationally, we wanted to transplant the energy, the single-mindedness, and maybe some of that risk profile into Edwards," he notes. So following the PVT acquisition, Edwards created a separate organization encompassing all of the company's percutaneous valve research under the leadership of Stanton Rowe, who previously headed PVT.

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"One of the things that impressed me is the way Edwards, as a company, embraced a disruptive technology," says Rowe. "Many companies do an acquisition, rip out the technology they really were after, and bring that in-house, or they put up a wall between competing technologies and say, 'We're going to fight this out.' But Edwards' goal has always been to integrate the two companies."

What attracted Edwards to PVT, according to Mussallem, was both its strong IP portfolio and its early clinical experience. "There's something very valuable about clinical experience that you simply can't learn when you're in the [pre-clinical] lab," he points out. "We decided that our commitment to heart valve disease was such that we were willing to take the risk, knowing that this might not happen." Indeed, the one area of consensus among physicians and industry executives regarding percutaneous heart valves is that they are at least several years away from commercialization, perhaps as late as 2010.

Critics of the PVT deal charged that Edwards paid too much for a company that is a long way from having a marketable product. Mussallem shrugs off such criticism. "This is one of those deals that, if it doesn't pan out, we will have dramatically overpaid, and if it works, we will have dramatically underpaid—there will be no middle ground," he says.

As to why Edwards didn't hedge its bets, following common practice today of doing a small investment in PVT and structuring the acquisition based on milestones achieved, Stu Foster notes that such an earn-out model is best suited for companies looking to buy an individual product, as opposed to a broader technology. "We were not interested in just buying a product," he explains. "We purchased PVT because we wanted a lot of things—technology, products, IP, relationships with clinicians, and interventional talent. So an earn-out deal didn't work for us. We wanted the whole thing now because we knew it would substantially add to our strategic capability, which was very important to us."

And indeed, others see the real value of the PVT deal coming from the start-up's IP portfolio. "The addition of PVT further strengthens Edwards' intellectual property position, but that value is not likely to be demonstrated until we start to see products hitting the market," says Timothy A. Nelson, research analyst who covers Edwards for Piper Jaffray.

Does an Ace Product Top a Full Bag?

Developing new interventional products is only the first half of the process that Edwards has started in motion; the other half is selling these products—most immediately, the *Lifestent* system, since percutaneous heart valves remain several years away—to new physician customers: interventionalists. "When we looked at the peripheral stent market, we felt that the growth segment was going to be with the interventionalists, not the surgeons," Stu Foster explains. As a result, Edwards has set up a separate sales channel for the cardiac cath lab.

The company has gone through some ups and downs on the sales side with the *Lifestent* system, resulting at least in part from the problems on the design and manufacturing end. The 2004 product launch was hampered by limited size availability and inventory constraints, delivering around $3 million in revenue with roughly a 30-person sales force. The original 2005 stent forecast was between $10-20 million range, but Edwards has missed each quarterly target this year. The company has re-forecast the revenue from the *Lifestent* system in the $7-8 million range and has scaled back its sales force to the mid-20s.

Another issue that Edwards is facing in opening this new channel by relying on a single device instead of a broad product line is how it can prove to be attractive both to new customers, e.g., interventionalists, who aren't familiar with Edwards, and to experienced sales reps accustomed to having a full bag of products. "There's a risk of trying to invest too quickly in a distribution system for peripherals before the company has a strong enough product or a big enough bag to ensure that the salesperson is welcome in the interventional suite," says Piper Jaffray's Tim Nelson.

Nelson questions Edwards' approach of building its peripheral business around one product—the *Lifestent* system—as opposed to developing a broad range of peripheral products. "The challenge for Edwards," he goes on, "is not getting overly-optimistic about how quickly they can build this business. You don't want to hire sales people without having products for them to sell." In Nelson's view, "There are many different elements involved in effectively treating peripheral vascular disease. This is a continually evolving clinical area and to be competitive in this space, Edwards is going to need a lot more than just one self-expanding stent."

Overall, Nelson is optimistic not only about Edwards' promising initial foray into the interventional market, but also regarding the company's continuing surgical fortunes. "They have a much brighter future on the surgical side than people give them credit for," he argues. Nelson argues that the surgical products market, particularly heart valves, is under-appreciated. "We're seeing more signs that the valve market is under-penetrated, and I believe it is going to start growing more quickly than it has," he predicts. Nelson believes Edwards will continue to be the leaders because it is innovating faster than its competitors, which will continue to provide a solid revenue base to fund new surgical and interventional products.

If Edwards can make headway in percutaneous devices while sustaining its leadership among its core surgical customers, the company should be able to uphold what has been a remarkable growth story since its spin-off from Baxter, including likely hitting the $1 billion revenue mark this year. Mike Mussallem proudly points to a range of financial milestones that the company has continued to improve upon since the spin-off. Edwards has gone from a 1% annual growth rate to 9% this year, and hopes to top 10% on a routine basis going forward. Average gross profit is up from 44% in 2000 to 62% this year, with a goal of 70% that Mussallem doesn't think is that far away.

Asked what he thinks Edwards' product mix will look like five years from now, Mussallem reflects that, in a certain way, the company may not look all that different, just as Edwards today is remarkably similar to the spin-off company. For all the changes that have taken place since the spin-off, e.g., the divesting of its perfusion, ventricular-assist, and AAA businesses, heart valves and critical care products still comprise nearly 80% of Edwards' revenue. Rather, the company's success reflects its ability to respond to changes in its core markets, neither standing still nor having to find wholly new sources of revenues.

Indeed, that is Edwards' answer to the innovator's dilemma. It has built and sustained its franchise by working closely with physician-customers, while making the necessary technological changes to keep pace with shifts in clinical care. Thus, while Edwards' customers may change, its business remains the same.