FROST & SULLIVAN

Growth, Innovation and Leadership eBulletin

A quarterly eBulletin from the people who bring you the Growth, Innovation and Leadership Global Congress on Corporate Growth

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Growth Objectives and How to Achieve Them

Executive Interview with
Corinne H. Lyle
President, Global Operations
Corporate Vice President
Edwards Lifesciences

We sat down with Corinne Lyle to discuss the growth objectives for Edwards Lifesciences and the means to achieve them.

1. What are the key growth objectives of your company and what kind of role does your group play in achieving them?

Edwards Lifesciences is a global leader in products and technologies to treat advanced cardiovascular disease, the global leader in acute hemodynamic monitoring, and the number one heart valve company in the world. We are focused on treating advanced cardiovascular disease with our market-leading heart valve therapies and critical care and vascular technologies. So, broadly, the growth of our company is based upon innovating and providing treatments that transform patient care. We are guided in our work each day by our credo: "Helping patients is our life's work, and life is now."

Edwards Lifesciences' top line growth objective for the company's revenues is in the double digits, and for the bottom line, our earnings per share goal for 2008 is an 11% to 14% growth rate.

To drive toward and meet these objectives, we must ensure that we have the appropriate infrastructure in place to provide our existing products, and also manage new product manufacturing and introductions. In my role as a corporate vice president and president of Global Operations at Edwards, I collaborate with my colleagues on strategic planning to ensure that we have the foundation, as well as the capacity, in place to address market demands.

For example, we recently opened a new heart valve manufacturing facility in Singapore, to complement our existing heart valve manufacturing sites in Irvine, CA, and Horw, Switzerland. The Singapore plant will not only help us address the demand for our heart valves globally, but it will also allow for more capacity at our plant in Irvine, enabling our staff there to dedicate more time and resources to manufacturing Edwards' new transcatheter heart valve. This valve can be implanted without open heart surgery, and is available commercially in Europe and via clinical trials in the U.S. and Canada.

The other role our operations group plays is to continue to drive productivity and efficiency, which helps to improve profitability. We accomplish this by employing LEAN methodologies. By running a LEAN operation, we are trying to utilize the same number of people to produce more products. We began a LEAN initiative in 2006, and last year it resulted in a number of operational efficiency gains of more than 50%, and a cost savings of nearly $4 million.

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2. Which internal or external growth strategies have had the greatest return on investment?

Edwards' strategy is to provide transformational innovations, coupled with world class training and education, to address unmet clinical needs within advanced cardiovascular disease. With this in mind, Edwards has engaged in a very deliberate process of M&A transactions starting at the spin-off from Baxter in 2000, when Edwards became an independent, publicly-traded company. We knew we wanted to be a more rapidly-growing company, and realized we didn't have the portfolio to achieve this goal. Over the years, we have been refining our portfolio to be more growth-oriented and profitable, focusing on providing higher-margin, clinically differentiated products in areas where we could be the global leader.

People usually think of external growth as growing by acquisition, but to Edwards, this also means improving by divesting lower-growth businesses so that we can focus on higher-growth businesses. We have utilized a strategy that is a hybrid of internal and external growth, divesting and investing in each area, and this approach has provided great returns for us.

Just a few years after the spin-off, we felt we had the portfolio better aligned with our strategy and moved into our current phase, which is focused on making strategic enhancements to our portfolio. This strategy has worked well: our margin at the time of the spin-off was about 44 percent, and now, Edwards' gross profit margin is more than 65 percent. A big part of this improvement is our stronger product and business portfolio. This most recently includes the additions of Percutaneous Valve Technologies, Inc. – a transaction that provided substantial intellectual property and a significant head start in terms of clinical and patient experience with the transcatheter heart valve; and CardioVations – an acquisition that immediately supplied double-digit growth, was synergistic with our existing operations in cardiac and minimally invasive surgery. This provided an opportunity to drive new product innovations and growth through additional investments in R&D.

It's important to note that not every initiative is going to be successful. We know you will start with more than you will finish. We have prided ourselves in making the tough call to exit an initiative when it appeared that we would not attain the goals we set for it, such as achieving leadership or transforming medicine. This is a living process, and we will re-direct our energies to the best opportunities as we gain experience.

3. What can you do to ensure successful execution?

Successful execution is really all about talent. Talent is essential for sustaining long-term success.

During the last several years, we've gone through a lot of changes at Edwards: we've upgraded quality systems and put in a new, $20 million company-wide enterprise resource planning (information technology) system. This global integrated system supports Edwards' long term growth plans.

When you go through this kind of revolutionary change within the company – instead of step-by-step, evolutionary change – you have to be really attentive to what your people are saying. It's also important to identify the key talent within the organization by identifying who will act as leaders at these critical times, and incentivize them appropriately.

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We have a lot of systems in place to drive execution by engaging our talent at a high level. One tool that we use regularly is anonymous employee surveys, which help us determine the level of employee engagement and target areas for improvement. We utilize the feedback from the surveys to make adjustments to our priorities or implement other changes that are important to employees.

One practice that we always encourage is continuous communication with employees at all levels. We want all Edwards employees to know what the company's overall, long term strategy is, what our annual Key Operating Drivers are, and what their individual Personal Management Objectives are. We utilize communication to drive alignment among all three of these.

4. How do you nurture executive talent to drive growth?

In addition to the practices of identifying key talent and encouraging open communication, we also provide opportunities for emerging talent to learn and develop. Edwards creates training opportunities that help leaders develop around their interests, passions, and career goals.

In the organization within Edwards that I manage – which includes several shared services like IT, global supply chain, quality and regulatory affairs, as well as operations – there is overlap between, for example, IT, global supply chain and to a certain extent, quality. That overlap provides opportunities for people to move within my organization into different functional groups, and this helps them broaden their experience.

There are also opportunities for our employees to move around the globe. We have operations in North America, the Caribbean, Europe, and Asia. We bring people from abroad to do rotations at our headquarters in Irvine, and send people from Irvine to our international locations. Both the exchange employees and their co-workers at home and abroad learn a lot from their experiences.

5. Please describe the challenges within your industry and company to achieving growth objectives and what kind of strategies are you implementing in an effort to overcome growth challenges?

The biggest challenge our company and industry faces is the healthcare environment, and the continued pressure on the healthcare industry to drive down costs. Decisions about cost and reimbursement have implications for medical device companies, as unilateral cuts may not take into consideration either the outcomes or benefits of new medical technologies. This ends up being challenging and can negatively impact patient care.

Another area that presents new challenges is the U.S. Food and Drug Administration's (FDA) changing requirements to raise the bar on quality systems. Companies like Edwards are required to make significant investments in quality systems to simply keep up with regulations, and these requirements can be costly. Last year, we spent several million dollars to upgrade our quality systems to adhere to the regulations. Edwards has high quality, premium products and we are committed to maintaining this level of excellence. Nonetheless, the FDA required us to bring a number of processes for existing products – some developed decades ago – up to current standards, which required substantial incremental investment.

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Our best tool in overcoming these challenges is communication. As an industry, Edwards and our peers need to continue the dialogue with each other, with the government and with regulators to make sure they understand the issues we as an industry face, as well as the issues faced by our stakeholders, such as patients and employees. You can't presume people understand what the challenges are unless you talk about them a lot, you inform people how to address the issues and you educate them on why it's important to be sensitive to them.

6. How has globalization affected your company's ability to (a) innovate and (b) grow its businesses?

Similar to many other medical technology companies, about 90 percent of our sales today come from the United States, Europe, and Japan. There is still great opportunity for growth in our major markets, especially outside the United States.

The most interesting growth opportunities for Edwards over the next several years will be in Europe, due largely to the region's regulatory climate. As an innovator, our company's products tend to be based on new technology, and new technologies tend to become available in Europe first. Thus, we expect our sales in Europe to grow quickly over the next several years, and this environment also brings many important benefits to European patients.

In terms of innovation, the various regulatory molds in the countries around the world are different. Once you achieve a product approval in one country, it doesn't mean you can necessarily piggyback on that to get approval elsewhere. This is especially true in Europe – even though you have an EU CE Mark for a medical device, you have to go country-by-country to get reimbursement. So while they're trying to make headway in terms of more unification across Europe, it's still very regional, and decisions are still made on the local level in much of Europe.

In Japan, we have a very strong and long term customer-based organization. However, the Japanese medical device approval process traditionally has been much longer than elsewhere in the world, so our colleagues there face a constant challenge to deliver lifesaving technologies to Japan as rapidly as possible. Often this comes years after the same products are available in Europe and the U.S. As we're able to move new products to market there, we see our business in Japan as a nice growth driver.

We also find that the emerging markets that make up that remaining 10 percent of our business represent the fastest-growing portion of it. We think that's very exciting, and we're making investments in those markets. As they develop economically, they are able to access our advanced technology – and we look forward to entering these markets when the opportunities are right - and related to intellectual property protection and the political environment.

7. What kind of initiatives do you recommend to monitor and counter external threats to a company's strategic objectives?

Patients are expecting more innovation, while at the same time wanting more careful oversight and regulation. They expect technology that is high-quality, high-performance, and safe. As an industry, medical device companies need to be aligned around these priorities, and work together to take on common issues and promote the latest technologies.

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One issue we currently face is the misconception that medical technology is a contributor to rising healthcare costs. There was a recent study published by Roland "Guy" King, former chief actuary at CMS, that showed only 6 percent of total national healthcare costs are related to medical technology, and the rate of increase of these costs is much less than the CPI or medical CPI. We believe that our technologies can help produce solutions to these issues. New technology addresses unmet needs and saves money. There's a great opportunity for new technology to change the way that medicine is practiced.

In keeping with this, it's important for companies to be able to demonstrate a technology's economic viability in addition to strong clinical data. In the past, manufacturers were only focused on achieving FDA approvals. But now, it's not uncommon for Edwards to collect economic data as we go through our clinical trials.

It is also important for us to find a way to ensure the protection of our intellectual property assets and know-how outside of the U.S. The ability for companies like Edwards to continue to innovate important medical devices is best supported by an environment that protects and rewards this innovation.

There are unmet patient needs worldwide that could be fulfilled by the products made by Edwards and our peers in the medical device industry. The global community's interest in communicating on these important issues, and making changes, where necessary, can go a long way in removing the barriers that currently prevent our technologies from helping their citizens live longer, healthier, and happier lives.